S. HRG. 106–420

USE OF SECLUSION AND RESTRAINTS IN MENTAL HOSPITALS

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

OCTOBER 26, 1999

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE

63–234—CC WASHINGTON : 2000

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402

ISBN 0-16-060423-0

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EXAMINING THE USE OF SECLUSION AND RESTRAINTS IN MENTAL HOSPITALS

TUESDAY, OCTOBER 26, 1999

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:11 a.m., in room 215, Dirksen Building, Hon. William V. Roth, Jr. (chairman of the committee) presiding.

Also present: Senator Moynihan.

OPENING STATEMENT OF HON. WILLIAM V. ROTH, JR., A U.S. SENATOR FROM DELAWARE, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The meeting will please be in order.

I apologize to our distinguished guests, the two Senators from Connecticut. You have been waiting, I know, a long time. So I thought what we would do, is go ahead and start with you, and then we will make our opening statements. That way you will miss our golden words.

Before we do that, I do want to take a moment to remember the great man who sat in the empty chair next to me, and to consider the tremendous influence he had, really not only on this committee, but on the Senate as a whole.

I think the past 2 days have been very difficult days for all of us, as we have lost a dear friend, a dear colleague. Our thoughts are with Ginny and the Chafee children and grandchildren as they mourn the loss of the man that they loved.

Many of us here knew of John's desire to retire and return home after what has been an unparalleled legacy of public service. From the shores of Okinawa, to the State House of Rhode Island, to the U.S. Senate, Capitol Hill, John Chafee lived the life of a patriot and a statesman.

Pat, I think he served an example for all of us, showing how a clear vision, the ability to build bipartisan cooperation, and a steadfast desire to represent the people back home are, indeed, the ingredients of a very distinguished career.

John will be missed by this committee, he will be missed by me, and I am, indeed, grateful for his friendship, his advice, and leadership through the years.

Senator MOYNIHAN. Mr. Chairman, I have no words as eloquent as yours. We were 23 years together in this committee, and for my case also in Environment and Public Works.

The French have a term "famille éteint," the ending of a great house. I would hope not. I would hope Lincoln will carry on. It is a large inheritance, great tradition, from Guadalcanal to the U.S. Senate.

A man of such extraordinary self-effacing gentleness for a Marine, a rifle company captain. He knew more about violence than most people will ever know, and was more gentle than any of us will ever see. We will talk about him more.

The CHAIRMAN. Thank you, Pat.

It is now my pleasure to call on Senator Dodd.

STATEMENT OF HON. CHRISTOPHER J. DODD, A U.S. SENATOR FROM CONNECTICUT

Senator DODD. Thank you very much, Mr. Chairman. I am pleased to be before you and Senator Moynihan this morning, along with my colleague Senator Lieberman.

Allow me just to add my words as well. I first got to know John Chafee as a college student in Providence, Rhode Island when he was the Governor of that State, and admired him and enjoyed working with him over the years.

I mentioned yesterday when I talked to Ginny, truly, to be a scholar/athlete/soldier/statesman, we use those words to describe an awful lot of people, but they so aptly apply to John Chafee. You would not have known about his accomplishments in any of these areas had you relied exclusively on John telling you about them.

He was so self-effacing, as Senator Moynihan has said, so gentle, kind, and so committed to improving the lot and quality of life of other people, that this institution will miss him. But, more importantly, the country truly will miss his abilities, a true legislator, who understood the art of compromise.

So I am deeply saddened this morning to be appearing before this committee and not seeing John Chafee here, a person who cared about the kinds of issues we are going to talk about today, and whose voice and vote would have been welcomed in these matters.

At any rate, to both of you, we thank you immensely for the opportunity to appear before you.

Mr. Chairman, let me just begin by reading something to you that appeared in a series of articles written in the Hartford Courant, which really provoked, I think, more than anything else, mine and Senator Lieberman's interest in this subject matter. We certainly were aware of this, but never as pointedly as brought out by a series of articles that appeared back last year.

This is by Eric Weiss, with reporting by Dave Altimari, Dwight Blint, and Kathleen Meegan. "A Nationwide Pattern of Death," it is called. I will just read you the first couple of paragraphs.

"Rochelle Clayborn pleaded for her life. Slammed face down on the floor, Clayborn's arms were yanked across her chest, her wrists gripped from behind by a mental health aide. 'I can't breathe,' the 16-year-old gasped. Her last words were ignored. A syringe delivered 50 milligrams of thorazine into her body, and with eight staffers watching.

"Clayborn became suddenly still. Blood trickled from the corner of her mouth as she lost control of her bodily functions. Her limp

body was rolled into a blanket, dumped into an 8 x 10 room used to seclude dangerous patients at the Laurel Ridge Residential Treatment Center in San Antonio, Texas. The door clicked behind her. No one watched her die."

I will ask unanimous consent that the rest of these articles be included in the record for the benefit of the members of the committee who may be interested.

The CHAIRMAN. Without objection.

[The articles appear in the appendix.]

Senator DODD. Mr. Chairman, 12 years ago, this committee took the courageous step of passing legislation that regulated the use of restraints and seclusion in nursing homes.

As a result of your efforts, today nursing homes are a far safer place for older Americans. Now we are faced with an opportunity to do the same for individuals with mental illnesses.

As pointed out by the Hartford Courant articles, Mr. Chairman, and the General Accounting Office, when investigating the use of seclusion and restraint, more than 150 deaths have been found directly attributable to the misuse of restraint and seclusion over the past decade.

Equally tragic, however, are the nameless and faceless individuals who are killed or injured by abusive restraint and seclusion practices that we never learn of. In fact, both the Hartford Courant articles and the General Accounting Office determined that there is no way presently to determine exactly how many people with mental illnesses are killed or injured due to the misuse of restraints or seclusion each year.

The Harvard Center for Risk Analysis estimates that as many as 150 deaths per year may be caused by restraints or seclusion. The deaths we are aware of are most likely just the tip of the iceberg.

This is a tragedy, and with your help we are going to end, we hope, these abusive practices. We did it for patients in nursing homes, as I have mentioned, and we should do it for individuals with mental illness.

The two bills that Senator Lieberman and I have introduced differ in some respects, but taken together, these two bills share a common core. They create, through new limits on the use of potentially lethal restraints, be they physical or chemical, rules for training mental health care workers and they increase the likelihood that a wrongful death of a mental health patient will be investigated and possibly prosecuted, not ignored as too often has been the case in the past.

Our legislation simply seeks to put an end to the shameful record of neglect and abuse of some of our Nation's most vulnerable and least cared for individuals.

The provision that this committee passed a dozen years ago that helped stop the negligent and abusive treatment of nursing home patients was a simple measure that established strict guidelines on how and when restraints and seclusion could be used.

Both mine and Senator Lieberman's legislation start by extending that same protection to the mentally ill. In particular, our bills, taken together, do the following three things.

First, they set standards for restraint and seclusion use. Physical and chemical restraints may be used only when a patient poses an

imminent risk of physical harm to himself or others. No longer will the use of restraints or seclusion for reasons of discipline, punishment, or convenience be tolerated.

This is accomplished, Mr. Chairman, by extending to the mental health population the existing standard enacted by this committee as part of the 1997 Omnibus Budget and Reconciliation Act, and is already proven effective in reducing the restraints in nursing homes.

Second, we help ensure that providers who violate the rights of the mentally ill will be held accountable. Our bills would require the facilities serving the mentally ill to report all deaths as a result of seclusion or restraint to an appropriate agency, as determined by the Secretary of Health and Human Services, for oversight and investigation.

They will also grant the Secretary of Health and Human Services the authority to end any Federal funding for mental health care providers who violate the protections this bill establishes.

Last, Mr. Chairman, we will ensure adequate safe training in staff levels. It is disgraceful, Mr. Chairman, that mental health workers are consistently the least trained and least well paid of any people who work in the health-related fields.

Presently, there are no uniform or minimum Federal training standards for mental health care workers. In many States, there are stricter standards, quite candidly, for the care of pets than there are for the care of the mentally ill in this Nation, these vulnerable children and adults.

Our legislation would help ensure adequate staffing levels and appropriate training for staff facilities that serve the mentally ill. Specifically, our legislation requires the Secretary of Health and Human Services to set regulations requiring mental health providers to adequately train their staff in the correct application of restraints and alternatives to ensure that appropriate staffing levels are maintained.

Mr. Chairman, the Compassionate Care Act, S. 750, the one bill that I have introduced with my colleague as the co-sponsor, was reported favorably out of the Health and Education Committee by a vote of 17 to 1 as part of the SAMSA legislation, which I know both of you are familiar with. It is due for reauthorization. So, we are hopeful to be able to have a vote on that, that piece of it.

But the other piece of it comes directly before this committee. I am going to leave to my colleague Senator Lieberman to describe the importance of this committee's role in the comprehensive version of the legislation in the two bills that we have introduced.

Mr. Chairman and Senator Moynihan, we are here today to share with you and to offer a solution on something that we think we can do that would save lives and protect these innocent, vulnerable people.

Senator Lieberman and I urge the committee, and the entire Senate, for that matter, to do for individuals with mental illness what we have already done, as I mentioned at the outset, for those living in nursing homes.

These vulnerable, precious human beings who are caught in the web of mental illness deserve, at the very least, just our sense of compassion. That this would happen to Rochelle Clayborn should

never happen again to another individual in this country. We hope that, with your support and help, we can do something about it. We thank you for listening.

The CHAIRMAN. Thank you, Senator Dodd.

Senator Lieberman, welcome.

[The prepared statement of Senator Dodd appears in the appendix.]

STATEMENT OF HON. JOSEPH I. LIEBERMAN, A U.S. SENATOR FROM CONNECTICUT

Senator LIEBERMAN. Thanks, Mr. Chairman and Senator Moynihan.

If I may, let me just, first, join in the tributes to our friend and colleague John Chafee, and our condolences to Ginny and his family.

At moments like this, particularly when we lose someone unexpectedly, I know we are not only all shaken, but we are reminded that, beneath all of the headlines and the controversy, the Senate is 100 people working together.

When one who was as central to that effort as John Chafee was departs, it is felt by all of us. It seems to me, thinking about him this last day or so, that he managed to be a classic New England individual: sturdy, principled, straight-talking, and yet also combine that with a great loyalty to this institution.

In other words, his individuality did not, as great as it was, surpass his appreciation and loyalty to the institution in his effort to make it work. He was uncommonly good, as we all know, at finding common ground among us without, if I may say so, losing his own individuality. That is a gift, and made him a great legislator. It was my privilege to work with him for the 11 years I have been here on the Environment and Public Works Committee.

Senator Moynihan, of course, has been a leader in that committee with Senator Chafee, and it is appropriate to have flowers in his chair because I do not know anyone in my time here who has done more to protect the great natural resources of the planet and the environment than John Chafee, who, working together with Senator Moynihan, fashioned some of the most progressive and extraordinary transportation legislation that this country has seen, which I think is some of the best work government has done, if I may say so, in the whole post-war period.

So we will all miss him very much, and hopefully we will be inspired by his career to also appreciate the institution and the importance, as Senator Dodd has said, of legislating as we go forward.

Mr. Chairman and Senator Moynihan, I am very grateful for your decision to hold this hearing on the use of restraints. You did not have to do it and I appreciate very much your decision to do it.

The reports that we have received, first, from the Hartford Courant, other newspapers in Connecticut, and then from the GAO, really rolled back a door on what seems almost like a medieval world, where facilities and providers are not being held accountable for what have to be called some barbaric practices.

This year, over 240,000 individuals will be institutionalized in our country for mental health care. The GAO notes in its report on

this subject, "The safeguards currently in place are not comprehensive and fail to fully ensure the rights and safety of these individuals." Two hundred and forty thousand individuals.

The GAO, in fact, has identified at least 24 mental health patients that died last year under restraints and seclusion in mental health institutions in our country, and that number, GAO acknowledges, is clearly an under-estimate because there are so few reporting requirements, although its findings surpass the number of deaths on an annual average basis uncovered by that searing set of articles, eye-opening set of articles in the Hartford Courant last year. The Courant discovered that over 142 patients died over a 10-year period in the last decade in mental health institutions because of restraints and seclusion.

The more I have come to learn about this subject, the more I have concluded that many of those deaths were needless. I honestly believe that they can be stopped if we hold the facilities and the staff accountable for their use of restraints and seclusion.

If restraints are going to be used and people are going to get injured or worse, families and the community, friends, have a right to know the circumstances of the injuries and the identity of the facilities where deaths occurred before their loved ones enter those facilities.

The legislation that Senator Dodd and I have introduced, along with other members of the Connecticut delegation, is based on that fundamental commitment to accountability.

Under the legislation, no person will be placed in restraints by a nameless health care provider in the middle of the night, or at any other time of the day, behind a wall of secrecy that family and friends cannot penetrate.

If restraints are to be used, a physician or a licensed independent practitioner will have to sign the order. That person will be held accountable for serious injuries or deaths that occur under his or her authority.

Under our legislation, the public will have an absolute right to reports of deaths from restraints and seclusion. No facility will be able to conceal a record of these deaths or injuries from the families of the mentally ill, or the parents of an individual seeking care for their loved ones.

I am very grateful that our proposal has received support from a large and varied group of organizations, including the American Health Care Association, the American Psychiatric Nurses Association, Basilon Center for Mental Health Law, Joint Commission on Accreditation for Health Care Organizations, the National Alliance for the Mentally Ill, the National Mental Health Association, and many others.

With your permission, Mr. Chairman, I would like to enter those letters of support into the record.

The CHAIRMAN. Without objection.

[The letters appear in the appendix following the Senator's prepared statement.]

Senator LIEBERMAN. Since the Hartford Courant articles were published and this problem has gained some public visibility, there has been a remarkable series of acts by organizations to prevent additional death and injury.

Most notably, I think the administration, through the Health Care Financing Administration, HCFA, which you will hear from this morning, has issued regulations which now limit the use of restraints in over 6,000 hospitals in our country.

Two committees of Congress, the Labor HHS Subcommittee of Appropriations and the Committee on Health, Education, Labor, and Pensions, have addressed the use of restraints through legislation and appropriations.

The legislation before you now in this Finance Committee goes to the heart of the problem, and I think offers a very comprehensive set of principles and protections. I urge you to consider it carefully, and hopefully to report it out as soon as possible so that further death and injury can be prevented.

I thank you very much for your attention and your courtesy in letting us proceed.

The CHAIRMAN. Gentlemen, thank you for being here. I appreciate your taking the time to testify on this most important and tragic matter.

Senator MOYNIHAN. Thank you, indeed.

The CHAIRMAN. For the past several months, as our two witnesses have already pointed out, there has been extensive media coverage of injuries and deaths allegedly resulting from the inappropriate use of seclusion and restraints in mental health hospitals.

These allegations are particularly disturbing, given that hospitals are supposed to be places of safety and healing of the sick. I think that is generally the case, generally true.

But, unfortunately, there are too many instances where, instead of promoting wellness, hospital practices can put patients at risk. So today we are trying to better understand the risks associated with seclusion and restraint, and to explore alternatives to minimize those risks.

I am very concerned about reports of deaths of adults and children resulting from the inappropriate use of restraints. As a parent and a grandparent, I cannot imagine the horror of putting your child in the hospital for needed treatment, only to have that hospitalization result in their tragic death.

So I think it is important that we hold these hearings. I believe all of us, lawmakers, regulators, providers, advocates, want the same thing. That is: To promote the health and well-being of vulnerable patients.

So, with that, I would turn to you, Senator Moynihan, for any comment you may care to make.

OPENING STATEMENT OF HON. DANIEL PATRICK MOYNIHAN, A U.S. SENATOR FROM NEW YORK

Senator MOYNIHAN. Thank you, Mr. Chairman. I am going to try your patience, which is legendary in any event, but to give sort of a background for the situation that we are dealing with.

I will leave the Senate next year with one of the mysteries to my mind—after 24 years of telling this story, it has had no impact of any kind on the fairness of the world—which is the story of the deinstitutionalization of the mentally ill.

I was present at the creation. In New York State at Rockland State Hospital, Nathan Cline began working in the 1950's on what would become the first tranquilizer. It was done by synthesizing the active ingredient of a tubular plant name rauwolfia, which is used in Veddick medicine, Indian medicine, over five millennia.

Averill Harriman was elected Governor of New York in 1954, and in 1955 he to chose a new Commissioner of Mental Hygiene. That term itself is descriptive, something about dirty thoughts or something like that. Jonathan Bingham, later to serve in the Congress, who was interested in this subject as were many others, brought in Paul Hoake, who had been head of our psychiatric school in the State system.

He suggested it was all sort of set up for Harriman to say, well, welcome, Dr. Hoake, what do you want to do? He said, we have got this new treatment, medication, a new idea, that we have been testing clinically and we think we should now use it system-wide.

Harriman said, well, how much will that cost? Paul Appleby was the head of the Division of the Budget. And Hoake said, about $8 million. Harriman asked his budget director, can we find that money? Yes, said the budget director. Good, said the Governor. I am an investment banker; I believe in these things.

There were then about 100,000 persons in mental institutions in New York State, and there are now about 8,000. The question is, where have they gone? The answer is, they have mostly gone to homeless shelters.

When President Kennedy took office in 1961, he had waiting for him a commission report, a Joint Congressional Commission on Deinstitutionalization. He had recommendations for community mental health care.

The President set up a three-department group, the Veterans Administration, HEW, it then was, and Department of Labor. I represented the department, having had this experience in New York.

The last public bill signing ceremony that John F. Kennedy had was the Community Mental Health Center Construction Act of 1963. I was present; he gave me a pen.

We were going to, by the year 2000, empty out the mental institutions. We are going to have 2000 community centers by the year 1980, and then build one per 100,000 ever since.

Well, we emptied out the hospitals. We built about 400 of these centers. The program got folded into another program, and then another program, and then finally disappeared. No one remembers it, no one misses it.

In my State of New York, with our ineffable capacity to get things wrong, we blame the problem of the homeless on the lack of affordable housing. Sir, it is called schizophrenia and it has a regular incidence in all populations.

These people are sent to various places at various times, obviously, and nothing like the ordered atmosphere of the community centers that were meant to be in touch with people, have them stay over when they had to, see that they had their medication, keep in touch with them.

It is an enormous health care failure. We are always running around looking for new ways to do new things about health, but

we pay no attention to this. End of oration. I will do one more next year, and that will be the last you will hear of me.

The CHAIRMAN. Thank you, Senator Moynihan.

The hour is growing late and we will now proceed with the witnesses.

First, we will call upon Mike Hash, the Deputy Administrator for HCFA. We are very pleased to have you with us, Mike, and I welcome your comments on HCFA, regulatory intervention on seclusion and restraints.

Please proceed.

STATEMENT OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, WASHINGTON, DC

Mr. HASH. Thank you, Mr. Chairman.

Chairman Roth, Senator Moynihan, distinguished committee members, we want to thank you for inviting us to discuss this important issue of preventing the inappropriate use of seclusion and restraint in psychiatric hospitals.

We applaud the efforts of Senator Dodd and Senator Lieberman, and Congresswoman DeGette in the House, who have proposed bills to address this issue. We, of course, recognize the important contribution of the journalists at the Hartford Courant on this issue.

We greatly appreciate the insights and advice that have been provided to us on this issue from the General Accounting Office. We, too, are profoundly disturbed by the reports of deaths and injuries resulting from the inappropriate use of seclusion and restraints.

We strongly agree with patient advocates and others that the use of seclusion and restraints in psychiatric care must be recorded, reported, and always a last resort.

We are taking steps to ensure that the use of restraints or seclusion to manage behavior is an emergency measure reserved for unanticipated severely aggressive or destructive behavior that places the patient or others in imminent danger.

We have removed certification from facilities where egregious violations of this kind have been documented, and we have a comprehensive review under way of facilities owned by the Charter Corporation because of the extent of problems that we have identified in this chain.

In July, which has been mentioned earlier, we mandated that all hospitals providing services to Medicare and Medicaid beneficiaries recognize specific patient rights, including the right to be free from inappropriate use of seclusion and restraints.

Under these important new rules, the following is required. First, seclusion and restraints may not be used in any form as a means of coercion, discipline, convenience, or retaliation.

Second, hospitals must report to us any death that occurs while a patient is restrained or in seclusion. We, in turn, will report that death to the State Protection and Advocacy Agencies for investigation.

Third, a physician or a State-approved, licensed independent practitioner must conduct a face-to-face evaluation for any patient

placed in seclusion and restraints for behavioral management within one hour of the initiation of such seclusion or restraint.

Fourth, hospital staff—and this has been emphasized by the two Senators earlier—must have training in the appropriate and safe use of restraints and seclusion.

Finally, hospitals must provide the patient or family members with a formal notice of the right to be free from inappropriate seclusion or restraints, and other rights at the time they are admitted to a hospital.

In addition to the reporting of deaths, we are also considering regulations defining serious injuries related to seclusion and restraint for which reporting should also be mandatory.

We are working with other Federal and State agencies to determine the best system for maintaining comprehensive records of seclusion and restraint incidents, and we are working to extend strong protections to individuals in residential treatment facilities, congregate care centers, and community-based settings.

We are also meeting the commitments which were made last summer by our Administrator, Nancy Ann DeParle. We have determined that we can extend similar protections to residential treatment facilities that are providing psychiatric services to individuals under the age of 21, and we expect to publish a regulation to that effect by this spring.

We will have interpretive guidance and answers to a list of frequently asked questions about the patients' rights regulation on our web site in the next few weeks, and we have a final hospital patient rights regulation that will also be published this spring.

Importantly, we will be working with the Joint Commission on the Accreditation of Health Care Organizations to improve their performance in monitoring the use of seclusion and restraints as a part of a broad accreditation action plan.

Already in August, we met one of our key goals for improving Joint Commission performance when the Joint Commission announced that hospitals will no longer be given notices of random surveys.

We believe our new regulations are a major step in directly addressing the inappropriate use of seclusion and restraints in mental health facilities. We intend to enforce them vigorously and to aggressively address the situations in which patients are endangered.

We, of course, look forward to continuing our collaboration in these efforts with you, this committee, patient advocates, provider groups, and State colleagues.

Again, I want to thank you for holding this hearing, and I am happy to answer any questions that you or Senator Moynihan may have.

The CHAIRMAN. Thank you, Mr. Hash.

We will, first, hear from Ms. Aronovitz, please.

[The prepared statement of Mr. Hash appears in the appendix.]

STATEMENT OF LESLIE G. ARONOVITZ, ASSOCIATE DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH ISSUES, GENERAL ACCOUNTING OFFICE, CHICAGO, IL

Ms. ARONOVITZ. Thank you, Mr. Chairman and Senator Moynihan. I, too, would like to acknowledge the untimely death of Senator Chafee. We were always inspired by his concern for the health and welfare of all individuals, and his attention and thoughtful approach to health care issues will certainly be missed at GAO.

I thank you very much for inviting us to be here today to discuss the impact of improper use of restraint and seclusion on people with serious mental illness or mental retardation.

These are among the country's most vulnerable citizens, as has been discussed. Because members of Congress became concerned about patient safety following an investigation by the Hartford Courant, GAO was asked to evaluate the risks involved, determine whether current Federal regulations provide sufficient protection, and explore how some States have found safer ways to handle potentially violent situations.

As we recently reported, improper restraint and seclusion puts people at risk, and even death. We found that at least 24 people died in fiscal year 1998 in incidents where restraint or seclusion was a factor. These were cases that were investigated by the Protection and Advocacy Agencies, or PNAs, and we believe that, because of reporting requirements that are very lax, and actually non-existent in many States, that the number could be much higher.

Until recently, Federal oversight had also been very limited. Although the Medicare and Medicaid programs provide about 20 percent of the funding for residential treatment of mental illness and mental retardation, Federal regulations governing restraint and seclusion use in facilities which receive such funding are inconsistent.

The Federal Government regulates the use of restraint and seclusion in nursing homes and intermediate care facilities for the mentally retarded, ICMFRs, but until recently there were no Federal regulations of these practices for hospitals, including psychiatric hospitals.

As Mr. Hash has described, in July of this year HCFA has revised the Medicare Conditions of Participation for hospitals to address restraint and seclusion use.

However, residential treatment centers for children and various types of community-based settings, such as group homes, are not presently covered. States have varying degrees of regulation on restraint and seclusion practices. Some only have detailed requirements for their State-run facilities, but not their private ones.

Many representatives of the hospital profession believe that voluntary reporting and internal review of deaths is the most appropriate way to control restraint and seclusion use.

However, we found, in talking to patient advocates and State officials, that the most effective oversight system requires both confidential internal review by the provider and reporting to an independent agency.

New York has had 10 years of experience with mandatory reporting of institutional deaths to their PNA. Hospital representatives

there indicated that this requirement does not compromise their ability to conduct confidential internal reviews for quality control.

In addition, mandatory external reporting can uncover patterns of risk. For example, as a result of the analysis of deaths from a number of treatment facilities in New York, the State outlawed two practices that had previously been considered appropriate types of restraint.

We found that it is possible to safely reduce reliance on restraint and seclusion. In Pennsylvania, the State hospital system's restraint and seclusion rates declined over 90 percent between 1993 and 1999. In Delaware, the State's ICFMR introduced an initiative that reduced its restraint rate by 81 percent in a 4-year period between 1994 and 1997.

Typically, successful strategies to reduce restraint and seclusion rates have similar components. They are a set of principles and policies to clearly outline when these measures can be used, strong top management commitment, reporting of restraint and seclusion use, oversight and monitoring, and intensive staff training in behavioral assessment, non-violent intervention, and safe restraint techniques as a last resort.

We acknowledge that HCFA has taken positive steps to ensure better reporting and patient protection through its new hospital conditions of participation. However, we believe more could be done to assure that Medicare and Medicaid beneficiaries with mental illness or mental retardation are protected from death or injury from the improper use of seclusion or restraint.

In our recently released report, we recommended actions that HCFA should take to ensure that patient protections regarding use of restraint and seclusion are provided to all Medicare and Medicaid beneficiaries in all types of residential care settings, and that serious incidents are reported. We are glad to know that HCFA officials are currently considering our recommendations, tailored, of course, to the unique needs of each population.

This concludes my prepared statement, and I will certainly be happy to answer any questions you have.

[The prepared statement of Ms. Aronovitz appears in the appendix.]

The CHAIRMAN. Thank you, Ms. Aronovitz.

Mr. Hash, since HCFA's regulation was released, I have heard from many health care providers expressing concern about your rule requiring a physician evaluation within one hour of the application of restraints.

Would you please comment on why you are requiring this on-site, direct, in-person evaluation?

Mr. HASH. Yes, Mr. Chairman. As we said earlier, these are circumstances that constitute an emergency in which an individual is at risk either for harm to themselves or harm to others. In such an emergency situation, we think it is appropriate that a face-to-face evaluation be made by a competent health care provider.

Our regulation provides that can either be a physician or a licensed independent practitioner that, under State law, is able to prescribe plans of treatment and interventions. So, it is not just a physician, it includes licensed independent practitioners as well.

The CHAIRMAN. Concern has been particularly expressed in the rural areas. What did you call them?

Mr. HASH. Licensed independent practitioners.

The CHAIRMAN. Practitioners. Would that include nurses?

Mr. HASH. It would include nurses that are prepared at the Master's level. Generally, States provide the authority for prescribing treatment to nurses and other advance-prepared practitioners who have education at the Master's level.

The CHAIRMAN. Now, the General Accounting Office recommends that the protections set forth in your new regulation be applied to all individuals treated in all facilities participating in Medicaid or Medicare.

Are you considering this?

Mr. HASH. Yes, Mr. Chairman, we are. In fact, we are actively working on the development of a regulation that will impose similar requirements on services that are provided under Medicaid to individuals under 21.

These are facilities that are so-called psychiatric facilities under 21. That is a site which we intend to impose a regulation this coming spring, and we want to apply the same kind of standards that we put forth for the hospital setting.

In addition, we are evaluating the application of appropriate requirements for patients who have served in community settings. As Senator Moynihan pointed out, many individuals with mental illness are, in fact, treated in home- and community-based service waivers under Medicaid, and we are looking at that setting and the kinds of protections that would be required for individuals receiving treatment there.

The CHAIRMAN. Ms. Aronovitz, there are some representatives of the hospital industry that recommend that there be voluntary reporting instead of mandatory. Do you agree?

Ms. ARONOVITZ. We really believe that mandatory reporting is very important. The people who feel strongly about voluntary reporting believe that, if you have mandatory reporting, it might discourage people within a hospital environment to be open and honest about what their restraint and seclusion use is, and they might actually even cover up some of their incidences.

We found this not to be the case in New York, where they have had a longstanding reporting requirement for their State hospitals. As a matter of fact, in talking to officials in New York, they felt that having to report, having a mandatory reporting requirement, is a natural way of doing business now, that people are not concerned about covering up.

In fact, having to report to an external body gives the opportunity of having a global view of what is going on in various facilities to assure that there are no outliers, and if there are, that those outliers are investigated and explained. So, we think this is a very important provision.

The CHAIRMAN. Senator Moynihan?

Senator MOYNIHAN. Thank you, Mr. Chairman.

I just want to continue on a theme. Ms. Aronovitz, you mentioned the New York State mental hospitals. We do not have any anymore. I mean, there are one or two, but in the main, they are

just derelict and empty. I do not think anybody is trying to take a global view of this situation.

We have had a great transformation that came about with the development of medication. And I believe, the time President Kennedy signed that legislation, there were about half a million persons in mental institutions in the United States. That was a long time ago. I think there are about 90,000 today; is that about right?

Ms. ARONOVITZ. There are actually about 120,000. I am sorry. There are about 240,000 people in inpatient treatment, residential treatment centers, or in group homes. They are not necessarily only in State institutions.

Senator MOYNIHAN. That is what I mean.

Ms. ARONOVITZ. Yes.

Senator MOYNIHAN. Somehow, we emptied out the mental institutions and somehow we have stopped building those community centers. We had a national plan and we forgot about it. That is all, we just forgot. Then we worked it out in various ways. Mr. Hash refers to The Charter Group. This is a for-profit enterprise?

Mr. HASH. Yes.

Senator MOYNIHAN. All right. Yes. And there are nursing homes, and this arrangement, that arrangement. There are also sidewalks. Lots of sidewalks. I would just hope we would take a look at what happened when we had this external event, the development of tranquilizers.

I mean, for all the talk about universal health care, surely there are no more needful group, Mr. Chairman, than the schizophrenic. They do not show up. We use new terms, like mental health consumers. That is from your testimony, sir. I am not getting critical, but what in the name of God is a mental health consumer?

Mr. HASH. It is an individual who is seeking services to treat their mental illness.

Senator MOYNIHAN. What if they do not know they have a mental illness, which is a condition of most people who are seriously mentally ill? Are they seeking it? You know what I am saying. That is all I am saying. But I think maybe the next President, instead of reinventing hospitals, will think about what happened to these people. Thank you.

The CHAIRMAN. Let me ask you one further question, Mr. Hash. May a physician bill Medicare for multiple visits in 1 day if the use of restraints renders multiple visits necessary?

Mr. HASH. Under our policy, Mr. Chairman, the initial face-to-face evaluation would be an event that they could bill the program for. The rules call for the provision of a plan of no more than four hours without it being reevaluated, but that reevaluation does not require the face-to-face encounter with a physician or limited licensed practitioner.

So, it is only within a period of 24 hours. If the restraint or seclusion is continuing to be renewed, it would be on the 24-hour period that it would have to occasion a face-to-face encounter. So I think the answer to that question is that physician encounters with patients in restraint or seclusion would be required once an every 24-hour period.

The CHAIRMAN. Well, thank you very much, Mr. Hash and Ms. Aronovitz. We appreciate your being here with us today.

Mr. HASH. Thank you, Mr. Chairman.

Ms. ARONOVITZ. Thank you.

The CHAIRMAN. Now I would like to turn to representatives of the provider community for their input. First, I am particularly pleased to welcome Mr. Dennis Klima, president and chief executive officer of Delaware's Bayhealth Mental Center.

Senator MOYNIHAN. Oh, Dover, Delaware.

The CHAIRMAN. So we appreciate having you here very much.

We also have Ms. Laura Prescott. It is a pleasure to welcome you here. And Dr. Charles Riordan, who represents the American Psychiatric Association. Finally, Mr. Terrence Johnson, who many of us recognize for the key role he played in appearing on 60 Minutes earlier this year.

So why do we not start with your testimony, Ms. Prescott?

STATEMENT OF LAURA PRESCOTT, EXECUTIVE DIRECTOR AND FOUNDER, SISTER WITNESS INTERNATIONAL, WORTHINGTON, MA

Ms. PRESCOTT. Good morning, and thank you for allowing me to speak with you here today. I am the executive director and founder of a new organization by the name of Sister Witness International, a new organization of formerly institutionalized women, girls, and their allies.

I am also a recovering addict and I will avoid the term consumer and use psychiatric ex-patient, and survivor of childhood abuse.

Research indicates that between 50 and 75 percent of the women and more than 25 percent of the men in the mental health system are survivors of physical and sexual abuse. Like many of them, I entered psychiatric treatment desperately searching for ways to be whole, to find words that could soothe and clarify the darkness of the past that endlessly seeped into the present moment.

All too often, I found more violence. The routine in the system left a trail of terror behind as I was often thrown to the ground by groups of men, staff and security guards, in a way that mirrored the violence of my past. Breathless and sweaty with anticipation, they took me down, in the presence of others, others who stood by, terrified and mute, dragging my body onto a bed and strapping it down in four-point restraint, forcing my legs apart in a position that replicated being raped. All the while, my body convulsed with the memory of violation as I was injected with high doses of medication.

Sadly, I had asked for help in creating a proactive program to help me with my anger prior to the onset of difficult times. I was told there was no place for my anger on inpatient units, that if I were too upset it would be too upsetting to the milieux, that if I were too overwhelmed I should take a pill to calm me down, to push the feelings down and away, to mask the symptoms rather than to heal the tragic, gaping wounds that made me so angry in the first place.

Each restraint sent the past into active presence, causing it to stand at attention, increasing shame, humiliation, and despair. It reemphasized or restimulated the futility of escape and the tenuousness of safety in the world.

These episodes often left me mute for days, and rather than deterring anything, perpetuated a vicious cycle. The more I was restrained, the more shame and humiliation I felt, the more shame and humiliation I felt, the more I disassociated, self-injured, and was restrained.

I am here today to testify to the shattering effects of these practices. It takes years to recover and, truthfully, nothing is ever quite the same. It has been 6 years since my last restraint, and I still wake in the middle of the night, my body soaked with sweat, my mind racing, the panic crowding the room.

I still hear the voices that pulsed down the hallways late at night, "Help me! Don't leave me here alone," as the hours were crushed into the pulp of stillness.

You may hear testimony by individuals who say that restraint helps them maintain control, that seclusion provides an opportunity to destimulate in an active environment. This rationale for the use of restraint and seclusion assumes there is a therapeutic benefit.

I submit that, if help is what people seek, there are many other successful ways to achieve that end. Seclusion and restraint are treatment failures, interventions of control, containment, and force.

When police are called onto units with loaded weapons in order to surround a flailing, half-naked woman and throw her to the ground, we have failed in our attempt to help.

I believe that we can seriously decrease costs of expensive hospitalizations, reduce the injury to staff and patients, if we support responsible, sensible alternatives to the polices of containment currently in place.

Creating environments that eliminate the use of seclusion and restraint has been accomplished in psychiatric facilities when administrators, policy makers, clinicians, clients, and advocates work collaboratively to implement innovative measures toward that end. By enacting the principles of least restriction, we can change the current cultures of coercion to environments that support dignity and empowerment.

Psychiatric facilities that have radically reduced or even successfully eliminated seclusion, mechanical and chemical restraint, have some key elements in common. Some of those include assessing individuals ahead of time for potential stressors, as well as things that have already been mentioned, like external monitoring of critical incidents, such as restraint, seclusion, injury, and death, cross trainings for individuals working in those systems, as well as investing in, and collaborating with, strong community-based services.

What I have learned from my experiences is that violence only teaches violence and indifference, and that it never teaches kindness and compassion. It is the antithesis of healing and true recovery.

Today, at the dawn of the new millennium, we have an opportunity to embrace a new history together, to become leaders by renewing our commitment to our most invisible citizens, by insisting that the business of mental health be a business that protects and defends human dignity and autonomy at all costs, because every life that is diminished diminishes us all.

I would be happy to answer questions, and thank you for listening.

The CHAIRMAN. Well, thank you for sharing with us your very moving experience. We will get to questions after we hear from the other witnesses.

[The prepared statement of Ms. Prescott appears in the appendix.]

The CHAIRMAN. It is now my pleasure to call on Mr. Klima, who is president and chief executive officer of Delaware's Bayhealth Medical Center. Most important, he is from Delaware. [Laughter.] So, Dennis, thank you for coming down. We appreciate it very much.

STATEMENT OF DENNIS KLIMA, PRESIDENT & CEO, BAYHEALTH, INC., DOVER, DE

Mr. KLIMA. Thank you, and good morning, Mr. Chairman and Mr. Moynihan.

Bayhealth is a full-service provider of health care to a diverse community, offering everything from inpatient and rehabilitation care to outpatient and long-term care, including behavioral health care at our St. Joan's Center.

Thank you for allowing me to appear before your committee today to talk about the use of restraint and seclusion at our St. Joan's Center.

Reports regarding the improper use of restraint and seclusion should concern everyone. I know I speak for hospitals and health systems everywhere when I say that we are all saddened when tragedy occurs. We are committed to finding solutions that prevent these unfortunate and troubling incidents.

Today, I want to make just three points. First, our number one priority at St. Joan's is the health and safety of individuals who come to us for treatment of psychiatric and addictive disorders.

These patients come to us at one of the most difficult and vulnerable times in their lives. They may be suicidal, have difficulty handling their anger, or suffer from mental illness or addictions. Patients come to us because their problems are so serious that they cannot be treated in other settings.

Often they are admitted because they are a danger to themselves or others. Patients' threat to themselves is real. The period act of restraining these patients prevents them from harming themselves or others. When used properly, restraint and seclusion can be a lifesaving and injury-sparing intervention.

However, we believe that restraint and seclusion should only be used when less restrictive methods are not feasible. My second point concerns Congress' clear desire to eliminate deaths and serious injury resulting from restraint and seclusion.

I believe, however, that overlapping legislation that mandates existing regulatory requirements would only serve to further complicate the efforts that are already under way. Clearly, there are, and should be, strong oversight mechanisms in place at the federal, State, and facility levels.

A wide variety of agencies are already empowered to inspect and sanction hospitals when a death or major injury occurs. We have worked with our State and our national associations to address this

issue in the private sector. We have developed guiding principles on restraint and seclusion for behavioral health services that include today's best practices.

On the government level, HCFA recently strengthened its oversight by issuing new restraint and seclusion standards as part of their Conditions of Participation. One advantage of these conditions is that they can be updated and improved, something not easily accomplished through legislation. Many of HCFA's standards in the Conditions also reflect best practices.

My last point, is my serious concern about HCFA's provision that requires a face-to-face physician evaluation of a patient within an hour of restraint use. That particular regulation is very troubling. It seeks to replace a physician's medical judgment with a regulatory requirement.

It is sensible to require a timely and clinically appropriate evaluation. It is not feasible, though, or clinically necessary, to require a face-to-face physician evaluation in every case, especially when many restraint and seclusion episodes last less than one hour.

I believe that the intent of the standard would be met by requiring the physician to evaluate the need for the order over the phone through prompt discussions with the nurse and responding in person when necessary.

This approach, combined with proper policies, education, and training, have allowed our institution to avoid injury for two and a half years at St. Joan's. We should not get in the habit of regulating medical practice or substituting unnecessarily a physician's presence for well-trained and qualified professional nurse practice and judgment.

In addition, implementing this provision is difficult to administer, may require substantial resources which are not reimbursed, and is difficult to meet because physicians may be asked to leave less stable patients to fulfill this requirement.

Finally, the regulation causes me grave concern because HCFA failed to consult with the hospital field in the development of this particular provision. In this case, HCFA's 30-day notice prior to the rule's effective date completely ignored the lead time needed for hospitals to change their operational policies and procedures.

If Congress must legislate, and we prefer that you do not, I respectfully submit to you that this one-hour rule should be reconsidered and redefined in any requirements that become law.

Mr. Chairman, I thank you for demonstrating your leadership by holding this hearing. I applaud Senators Lieberman and Dodd, and all Senators and Representatives who have turned their attention to this critical issue. I appreciate the opportunity to present my views and I would be pleased to address any of your questions. Thank you.

The CHAIRMAN. Well, thank you, Mr. Klima. It is a pleasure to have you here. We will have some questions later.

But, now I wold like to call on Dr. Riordan, who represents the American Psychiatric Association.

[The prepared statement of Mr. Klima appears in the appendix.]

STATEMENT OF CHARLES E. RIORDAN, M.D., ON BEHALF OF THE AMERICAN PSYCHIATRIC ASSOCIATION, NEW HAVEN, CT

Dr. RIORDAN. Good morning, Mr. Chairman. I am testifying today on behalf of the American Psychiatric Association.

The APA is a medical specialty society representing 42,000 psychiatric physicians in the United States. For the record, I am chair of the APA Committee on Standards and Surveys, as well as the APA representative to the Professional and Technical Advisory Committee of the Joint Committee on Accreditation of Health Care Organizations.

My written statement discusses in detail the recent report of the General Accounting Office, as well as legislation proposed by Senators Dodd and Lieberman, and particularly the problems with the new rules on seclusion and restraints published by HCFA on July 2.

Rather than repeat what is in my written statement, I want to focus my remarks on several key issues that I think will be helpful for the discussion. One, seclusion and restraint should not cause deaths. APA shares the concern of the Congress, the administration, and the public that special care be taken whenever psychiatric patients are put in restraint or seclusion.

Bluntly, death should never be the direct result of seclusion or restraint. Every effort should be made to ensure that seclusion and restraint are initiated in a safe, compassionate, and effective manner.

Seclusion and restraint should be used only when needed. We agree that seclusion and restraint should be used only when necessary for the safety of the patient, staff, or other individuals, and to prevent the complete disruption of the treatment environment.

These interventions should not be used when less restrictive interventions are appropriate for the individual patient based on the clinical judgment of the physician, in consultation with hospital staff. Seclusion and restraint should, likewise, not be used for punishment, for discipline, or for the convenience of staff.

It should be understood that today psychiatric inpatients are usually severely ill. For the most part, patients who require admission to a psychiatric hospital or a psychiatric unit today are seriously mentally ill and acutely mentally ill.

Symptoms include psychotic and delusional thinking, patients may hear terrible voices compelling them to acts of violence against others or themselves, they are sometimes abusive, combative, assaultive, and aggressive. They are frequently suicidal.

Many of them are dually diagnosed. That is, they suffer serious mental illness and are also alcohol and drug abusers. These are symptoms of their illness. If we fail, when appropriate, to seclude or restrain patients as the specific circumstances require, we risk assault, serious injury, and even death.

Congress and HCFA should help, not hinder, this process. We understand that Congress and the public want avoidable deaths and serious injury stopped. So do we. Congress and HCFA, together with Mrs. Tipper Gore, patients advocates, and the press have performed an invaluable service by bringing the issue of improper use of seclusion and restraint and the tragic consequences that can result to public view.

To ensure that we eliminate the inappropriate use of seclusion and restraint without creating new problems, we suggest the following. First, it is vital that we understand precisely what the problems are. The GAO highlights the fact that much is not known about deaths and injuries attributed to seclusion and restraints.

What is the scope of the use of these interventions throughout the population? Are the reported deaths and injuries due to inappropriate use, bad techniques, inadequate staffing? Are hospital procedures followed? What has been the response of facilities where they have happened? The truth is, no one knows.

We need to undertake a systematic and scientific top-to-bottom review of all these sentinel events to understand what the problem is. When we understand the problem, we will be able to craft solutions.

We believe we should consider reporting serious injuries, providing a viable, uniform definition can be agreed up. The Joint Commission reportable sentinel event definition of serious injury, not the Lieberman language, frankly, is a good start.

Third, staff education and training is a key element of any effective response. We strongly agree that staff should be trained in the safe and effective use of seclusion and restraints. Facilities should have sufficient staff on hand to ensure patients are handled safely.

Fourth, we need to avoid overlapping responses. We currently face new standards set by State legislatures, Congress, and HCFA. HCFA's new rules render House and Senate legislation largely redundant. Meanwhile, the Joint Commission is in the progress of field testing new standards.

Effective solutions, finally, cannot interfere with psychiatric physicians in the exercise of their independent medical judgment. The HCFA rule sets an arbitrary and capricious standard, requiring face-to-face physician assessment within one hour of the initiation of seclusion and restraints.

Various legislation include specific restrictions on seclusion and restraints. These are efforts to write standards of medical practice into law and generally are counter-productive.

By precipitously increasing hospital costs, they are likely to result in severely mentally ill patients being shifted into the forensic system, where they will get little, if any, treatment for their illness.

HCFA policies will require multiple physician assessments of individual patients on the same day. I would point out to you that, if I see a patient at 8:00 in the morning and I put them in restraints at 2:00 in the afternoon, I must see them again and there is nothing in the HCFA regulations which would allow a physician to be paid for that second visit.

Mr. Chairman, these variances between HCFA payment rules and mandated intervention need to be in sync. We welcome these hearings as a vital part of the public discussion of issues pertaining to the treatment of mental illness.

We look forward to working with you and your colleagues to reach our mutual goal of treating our patients with compassion and respect in a safe and human environment. Thank you.

The CHAIRMAN. Thank you, Dr. Riordan.

Now we look forward to hearing from you, Mr. Johnson.

[The prepared statement of Dr. Riordan appears in the appendix.]

STATEMENT OF TERRANCE JOHNSON, PHILADELPHIA, PA

Mr. JOHNSON. Thank you, Mr. Chairman. My name is Terrance Johnson. I am a licensed social worker with a Master's degree in social work from the University of Pennsylvania. Thank you for the opportunity to speak to you on the topic of seclusion and restraints.

Recently, I worked with the staff of CBS 60 Minutes documenting the dangers that exist in the children's ward of a psychiatric unit, but I believe that what I experienced while working undercover as a mental health worker may go far beyond that particular hospital and reflects the numerous deficiencies of a nationwide industry that often fails to provide quality mental health care.

At its core, this story was about children in need. I have seen these children in need enter and leave our hospitals without receiving help. I saw children spending weeks in a facility receiving little assistance to help them overcome, cope with, or even discover the issues that brought them to the hospital.

I saw how children who entered that facility spent the majority of their time with untrained mental health workers who lacked both the skills and the knowledge necessary to direct these children's recovery.

These mental health workers were well-intentioned people who were trying to make a living on the $8.32 that this hospital paid them. They seemed to be trying to survive their daily shifts with as few incidents as possible. Unfortunately, these mental health workers often found themselves in the midst of situations that they had not been trained to handle.

Typically, the untrained workers' only recourse is an authoritative paradigm consisting of an arsenal of commands, such as shut up, sit down, and calm down. Untrained, they order the children to be, and act, normal, warning that their failure to do so may result in seclusion or restraint.

At times, these untrained workers run these psychiatric units with little or no supervision, and with the unchecked authority to determine who gets seclusion and who gets restrained.

These untrained workers interact with children who are often living lives that many people in this room would find hard to imagine. Some lived in foster care, some were abused, many were teased relentlessly in school. These stressed, depressed, and suicidal children are locked in hospitals with untrained workers who demand strict compliance at all times.

Often, children and workers confront each other over rules and orders as mundane as standing in a straight line when going to gym or lunch. If the child refuses, a battle often ensues that may escalate to the point where the worker sends the child to seclusion or restraints.

I recall several situations similar to this. I recall these children confronting nearly surreal life situations, not having anyone to help them. I remember a specific child who would act out so that the workers would give him individual attention.

He only received individual help when he started hitting the walls or when he refused to take his psychotropic medicines. I can

still hear the words of the nurse: "You have 5 minutes. You either take this injection or you're going to get tied down." By tied down, she meant restrained.

I recall trying to talk to this child and being reprimanded by the managing nurse, who told me that we did not have the time or the staff to spend this much energy on one child.

If a restraint is not performed properly, a child can be hurt or killed. I observed restraints where none of the people performing the restraint had received any training on when the procedure was necessary or how it was to be carried out.

I observed situations where workers unknowingly handled the children in ways that led to injury for the workers and the children. A number of the restraints that I observed could have been avoided had the workers involved been properly trained.

In my experience as a social worker, I have seen the opposite of this environment. I have witnessed restraint-free environments where children grow and overcome the challenges that brought them into the hospital. In these environments, all the direct care workers are trained and have replaced the authoritative approach with educated compassion and empathy.

With the proper training, many seclusion and restraints can be avoided, but this will require raising health care standards across the board. This will require that every direct care worker receive the necessary training to carry out his or her jobs.

I believe that we can reduce the frequency of seclusions and restraints and improve the quality of care in mental health hospitals by making a few simple changes. One, provide clear guidelines that require that all staff be trained in the proper use of restraints.

Two, train all direct care workers in how to work with the population for which they are responsible. Three, require that any facility receiving Federal funding be independently monitored to ensure compliance with the national health care standards.

Thank you very much.

[The prepared statement of Mr. Johnson appears in the appendix.]

The CHAIRMAN. Thank you for your testimony, Mr. Johnson.

Let me start my questions with Ms. Prescott. First of all, let me again thank you for your openness. But let me ask you, do you worry that the focus on physical restraints could increase the use of chemical interventions?

Ms. PRESCOTT. Yes, Mr. Chairman, I worry about that quite a bit, which is why, in one of the bills, I was very pleased to see this morning it was spoken about when people referred to chemical restraint as part of restraint and seclusion. I was pleased to hear that.

I am very concerned about the substitution. If we simply take a look at this in terms of mechanical restraint, then we will see a number of individuals being chemically restrained as a substitute. I have seen that on the units that I have been on.

May I say one other thing?

The CHAIRMAN. Yes, please.

Ms. PRESCOTT. I am also concerned when we talk about dangerousness and the physical ramifications of seclusion and restraint, particularly mechanical restraints, that we also think

about the other kinds of ramifications of restraints, which are the other kinds of damage, which are psychological damage and retraumatization that happened to individuals who were restrained as well.

The CHAIRMAN. Mr. Klima, as you know, Delaware has been very successful in reducing the use of restraints in mental health facilities. Can you tell us how your own hospital has worked to limit the use of restraints?

Mr. KLIMA. Basically, at our institution we have had for some time, I think, good policies that include special education and training for our staff and requirements that that staff not only receive that training before they begin their work, but subsequently get reeducated and updated on a regular basis.

As a result, we can ensure that our staff, first of all, know how to help patients with alternatives before physical restraint or seclusion, and then in those circumstances when such restraint and seclusion is required, they are able to do it knowing, one, how to do it, the numbers of people they need, how to use the restraints, how those restraints work, et cetera.

I think having good knowledge and good collaboration as a team of people, from the physician to technician, they know how to work together and do it in a way that does not endanger the patient. I think that is why we have been successful in Delaware.

The CHAIRMAN. Can you give us any figures as to how much it has reduced the use of restraints?

Mr. KLIMA. Well, the only number I know of for our own institution is that, over the last two and a half years, we have reduced our utilization a little bit more than 50 percent.

With that reduction and the education, again, and knowledge is the key, but with that approach and a good, strong team approach where people are, indeed, held accountable and the physicians know when to respond in person and when not to, they are able to reduce the incidence of restraints and also to very much limit the potential risks of any restraints.

In fact, the only injuries I know of in our institution were not in a psychiatric setting, they were in the medical/surgical setting. They were what I would call not as terrible as some that we have heard about today. One was a broken finger, and one was a bruised arm. I am sorry that that occurred, and I wish it had not, but even that is better than some of what we have heard about.

The CHAIRMAN. But a 50 percent reduction is very, very significant. It sounds to me like we all could learn a lot from you.

Mr. KLIMA. Thank you.

The CHAIRMAN. Dr. Riordan, I understand your concern about the provision in HCFA's regulation that requires a physician or other licensed independent practitioner to perform an evaluation within 1 year of the use of restraint.

Given what we have heard about the risks associated with restraints, what alternatives would you propose?

Dr. RIORDAN. Well, first of all, Senator, I think that it is important to emphasize, as much as Mr. Klima did, the issue of staff training, the issue of minimizing the use of restraints, teaching staff alternatives to escalating violence well before we get to the point that restraints are implemented.

The question of the one-hour rule is a great problem, because I think that HCFA also requires that the attending physician be contacted at initiation of restraints. I think that is very important, because that is the person who understands what is happening to the patient.

The real issue with the one-hour rule, candidly, is that it is not going to be that physician that is going to arrive at 2:00 in the morning. It might be, frankly, a medical resident in a large teaching hospital who comes in at 2:00 in the morning after the psychiatrist has ordered the restraints at 1:00 a.m.

The question becomes, what is his role there? Is his role to assure that the patient does not die, as reported in the Hartford Courant series? I would suggest to you that the nurses taking care of the patient and continually monitoring the patient have assessed pulse, blood pressure, whether he or she is blue, and the physical situation of the patient.

Is that medical resident, who is a licensed independent practitioner, then to impose their judgment about whether this patient should be in restraint and seclusion when they know nothing about them at 2:00 in the morning, or are they realistically going to rely on the judgment of the physician who suggested that they be put in restraints that knows the whole case from front to end?

Now, this is what hospitals are going through. They are going to have these people come because everybody wants to comply with the HCFA rule. I do not think it does much to improve the care of patients, frankly.

I think it is the kind of bureaucratic difficulty that doctors and hospitals are facing, and with the restraints of the Balanced Budget Act on funding, something else will not be done because we will be doing this.

The CHAIRMAN. Let me turn to you, Mr. Johnson. You discussed the importance of training. Could you describe what kind of training you think should be required?

Mr. JOHNSON. Like I say, in the experience that I had, basically, there was no training or the training was haphazard. I think that the workers working with whatever particular population should have some training as to how to work with that population. Many times you see the workers get into struggles with children with various issues, or you see them get into struggles with adults.

But particularly with the children. Adolescents, at times, are very volatile and they snap at you. Many times, the workers would just snap back at them and it continues the struggle. The workers end up sending the child into seclusion.

So I think that the workers should be trained as to understanding the population that they work with, trained as to how to do restraints, and basically learn how to not bring their personal issues into a professional situation.

The CHAIRMAN. Thank you.

Senator Moynihan?

Senator MOYNIHAN. Thank you, Mr. Chairman. This has been moving and informative testimony, Mr. Johnson, Ms. Prescott, Mr. Klima.

I am very much impressed with what Dr. Riordan has told us. I do not know if you are familiar with this jargon, but in economics

you described what is called an opportunity cost; if you do this, you cannot do that. If HCFA has its way, there will be lots of them.

Their regulations are now, sir, three times the length of the Internal Revenue Code. Now, nothing is longer than the Internal Revenue Code. You would not have thought that possible. Well, our bureaucracies sometimes achieve the impossible.

I wanted to just ask a general question. Has the APA thought much about the deinstitutionalization phenomenon, and us seeming to have lost touch with it?

Dr. RIORDAN. I do not think the APA has lost touch with it, Senator. I was very struck by your comments. I started psychiatric training in 1964, and I trained in New York at St. Vincent's, which was one of the model programs under that Act. I know the 10 required services very well to this day.

Harvey Tompkins, who ran that program, became president of the APA, and I think the APA is still very committed to the issues that you have outlined and concern about community treatment opportunities in this country for the seriously and pervasively mentally ill is a critical issue before the Nation. I hope it is before the Nation.

Senator MOYNIHAN. I do not think it is. But that does not mean it cannot be. It once was. You made an interesting comment, very veiled, almost, about people who are hospitalized today, in this situation, were about 10 percent of the population that had previously been, and tend to be the more difficult and violent, or severe.

Dr. RIORDAN. Well, I think, if you think about it, they are probably the same population, if you consider the same population of illness that we have discharged into the community, for the reasons that you outlined, over 90 percent of those patients. So the patients we are left with are both ill and in an acute period of their illness. I think that is the point.

Senator MOYNIHAN. An acute period. And you mentioned the forensic alternative, which I believe is another word for jail.

Dr. RIORDAN. Yes.

Senator MOYNIHAN. And that can happen.

Dr. RIORDAN. I think you have been eloquent about that issue. I think, unfortunately, that is where our mentally ill have gone many times, the streets and the jails rather than to treatment facilities.

Senator MOYNIHAN. That is very right.

I hope we can continue this, Mr. Chairman. I think we have made promises we have not kept. We have a great profession. I mean, Benjamin Rush, I see, is your founder. There have been 100 years of the American Psychiatric Association. Much like other branches of medicine, it is only in the last generation that you have been able to maybe change things, through medication, in the main.

But we need your guidance. You are the professionals. You all have given your lives to this. We need the witnesses, like Mr. Johnson and Ms. Prescott. We need the managers like Mr. Klima. But this is not a blame game, and it too easily becomes that, sir.

Thank you, Mr. Chairman.

The CHAIRMAN. I could not agree more with you, Pat. What we are looking for are some solutions.

Let me thank each and every one of you for being here today. It has been most informative and helpful, and we will contact you further in the future. Thank you.

Senator MOYNIHAN. Thank you, all.

[Whereupon, at 12:10 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF LESLIE G. ARONOVITZ

Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss the effect of improper restraint and seclusion on some of the country's most vulnerable citizens—people with serious mental illness or mental retardation. About 5.5 million adults experience severe mental illness each year, about 240,000 of them requiring residential treatment in mental hospitals, centers, or group homes. In addition, an estimated 360,000 adults and children with mental retardation lived in intermediate care facilities or smaller residential settings in 1998. Medicare, the federal program of health insurance for the elderly and disabled, and Medicaid, the federal and state program of health insurance for the poor, help pay for the treatment of eligible individuals in these settings. Because members of the Congress became concerned about the safety of patients after a series of articles in the Hartford Courant reported on restraint-related deaths, we were asked to evaluate the risks involved in using restraint and seclusion, the adequacy of current federal reporting requirements and other protections, and what certain states had done to address restraint and seclusion.

In brief, as we recently reported, improper restraint and seclusion can be dangerous to people receiving treatment for mental illness or mental retardation and to staff in treatment facilities.[1] While there is no comprehensive system to track injuries or deaths, we found that at least 24 deaths that state protection and advocacy agencies (P&A) investigated in fiscal year 1998 were associated with the use of restraint or seclusion. We believe there may have been more deaths because only 15 states require any systematic reporting to P&As to alert them to serious injuries and deaths. We also found that federal and state regulations that govern the reporting of injuries and deaths and that govern the use of restraint and seclusion are not consistent for different types of facilities. The experience of several states demonstrates that having regulatory protections and reporting requirements can reduce the use of restraint and seclusion and improve safety for individuals receiving treatment as well as for facility staff. In our September 1999 report, we made several recommendations that, if adopted, should improve the safety of patients and staff in a variety of treatment settings.

Background

People with mental illness or mental retardation who receive residential treatment—and may be subject to restraint or seclusion—do so in a variety of settings. Psychiatric patients may receive inpatient treatment in traditional state hospitals, private psychiatric hospitals, or community hospitals with psychiatric units. The trend toward less restrictive community-based settings has led to more individuals with mental illness or mental retardation living in smaller facilities and group homes.

Federal funding through Medicare and Medicaid accounts for about 40 percent of the revenue for mental health treatment facilities. Medicare provides limited mental health coverage for individuals older than 65 and some individuals younger than 65 who are disabled. In 1994, Medicare spent about $4.5 billion for mental health services in private psychiatric hospitals and general hospitals. The Medicaid program covers certain low-income individuals for residential services to treat mental disabilities. Medicaid covers children and, at state option, aged adults with mental illness, and it covers adults and children with mental retardation. Medicaid provides inpatient mental health services for children younger than 21 in general hospitals, psychiatric hospitals, and nonhospital settings. Individuals aged 65 and older may re-

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[1] *Mental Health: Improper Restraint or Seclusion Use Places Patients at Risk* (GAO/HEHS–99–176, Sept. 7, 1999).

ceive inpatient mental health services in a hospital or nursing home. Medicaid spending for inpatient psychiatric treatment totaled more than $2 billion in fiscal year 1996. In the same year, Medicaid spent about $9.6 billion for intermediate care facilities for the mentally retarded (ICF–MR), which provide longterm residential care and treatment. In addition, Medicaid covers care for children with mental illness and adults and children with mental retardation through the home and community-based waiver program, which allow states to cover a broader range of services in less restrictive settings such as group homes. State Medicaid programs spent $5.6 billion in federal and state funding on home and community-based waiver services in fiscal year 1996, some of which was used to provide residential treatment. The federal government through the Health Care Financing Administration (HCFA) administers Medicare and HCFA and the states administer Medicaid.

Restraint and Seclusion Can Injure Patients and Staff

Restraint and seclusion present real risks of injury and death to individuals in treatment and the staff who care for them. Restraint is the partial or total immobilization of a person through the use of drugs, mechanical devices such as leather cuffs, or physical holding by another person. Seclusion refers to a person's involuntary confinement, usually solitary. Restraint and seclusion can be dangerous because restraining people can involve physical struggling, pressure on the chest, or other interruptions in breathing. Staff can be injured while struggling to get residents into restraints or seclusion.

Clinicians, providers, and patient advocates generally agree that when patients lose control to the extent that they or others are at imminent risk of being physically harmed, staff can legitimately restrain or seclude them in emergencies. However, many patient advocates, state mental health program officials, and representatives of the psychiatric physician and nursing profession disagree as to whether there is any other appropriate clinical use of restraint and seclusion or whether they should be used only as a last resort.

The dangers of restraint and seclusion have been recognized in the mental health community. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO), which accredits most hospitals participating in Medicare and Medicaid, recently sent an advisory to hospitals warning about the dangers of restraint and seclusion. JCAHO documented 20 deaths since 1996 caused by asphyxiation, strangulation, cardiac arrest, and fire while people were in restraint or seclusion. These were similar to the causes of death the Courant listed in its investigation, which included asphyxia, blunt trauma, cardiac complications, drug overdoses or interactions, strangulation or choking, and fire or smoke inhalation.

Children are subjected to restraint and seclusion at higher rates than adults and are at particular risk. Several of the states that took part in a study sponsored by the Department of Health and Human Services (HHS) Center for Mental Health Services reported higher restraint rates for children, including one state in which children in state-run inpatient facilities were restrained four times more frequently than adults. Children are smaller and weaker than adults are, so staff used to overpowering adults may apply too much pressure or force when restraining children. The following cases reported by the National Alliance for the Mentally Ill illustrate the dangers of restraining children:

- In February 1999, a 16-year-old girl died in California of respiratory arrest with her face on the floor while being restrained by four staff members.
- Basket holds—arms crossed in front of the body with the wrists held from behind were involved in the death of a 17-year-old girl in a Florida residential treatment center in November 1998 and the death of a 9-year-old boy in North Carolina in March 1999 after being restrained following a period of seclusion.

The use of restraint and seclusion can also result in serious injury and abuse. During fiscal year 1998, P&As received about 1,000 complaints regarding restraint and seclusion and documented instances of bruising and broken bones. In one instance, a 24-year-old man suffered a severe fracture in his right arm while facility staff were struggling to restrain him and was subsequently placed in four-point restraints and left for 12 hours with the broken arm, despite his requests for medical attention.[2]

Even if no physical injury is sustained, patients can be severely traumatized while being restrained, especially those who had previously been sexually abused. A Massachusetts task force reported that research indicates that at least half of all women treated in psychiatric settings have a history of physical or sexual abuse. The task force found that the use of restraints on patients who have been abused often re-

[2] Four-point restraints immobilize a person on a bed with a cuff around each wrist and ankle.

sults in their re-experiencing the trauma and contributes to a set-back in the course of treatment.

Restraint and seclusion can also lead to the injury of health care workers. The occupation of mental health care worker has been found to be more dangerous than construction work. Studies have documented that the largest percentage of patient assaults on staff members occurs during restraint or seclusion and that most staff injuries are sustained while staff are trying to control patients who are being violent.

Incomplete Reporting Leaves the Full Extent of Patient Risk Unknown

While restraint and seclusion can injure patients and staff, the full extent of that risk is not known. HCFA requires treatment facilities that participate in Medicare and Medicaid to fulfill certain requirements but before August of this year did not require hospitals—including psychiatric hospitals—to report deaths that might be associated with restraint or seclusion. The lack of comprehensive reporting makes it impossible to determine all deaths in which restraint or seclusion was a factor. However, through a survey of each of the P&As for the 50 states and the District of Columbia, we identified 24 deaths during fiscal year 1998 that were related to restraint or seclusion.

Reporting Requirements Are Not Comprehensive

Neither the federal government nor the states comprehensively track the use of restraint or seclusion or injuries related to them across all types of facilities that serve individuals with mental illness or mental retardation. Federal requirements on reporting injuries and deaths and restraint or seclusion differ by type of facility. Starting in August of this year, hospitals are now required, as a condition of participating in Medicare or Medicaid, to report to HCFA deaths that occur during—or can reasonably be assumed to be related to—restraint or seclusion.[3] Other facilities that provide residential services to mentally ill or mentally retarded individuals and that are paid by Medicare or Medicaid are not required to report such deaths to HCFA. Federal regulations require ICF–MRs and nursing homes to provide, during their regular oversight surveys, information that can be used for tracking the use of restraint and seclusion. However, there are no federal reporting requirements on the use of restraint and seclusion for any other type of facility, such as community-based group homes funded under the Medicaid waiver program or residential treatment centers for children.

Most states do not comprehensively track data on either the use of restraint or related injuries. Further, JCAHO recently surveyed states regarding their requirements to report sentinel events. "Sentinel event" is defined as an unexpected occurrence involving death or serious physical or psychological injury or the risk of such death or injury. While the results are preliminary, only half the states that had responded by March 1999 indicated that they had a law that required reporting sentinel events to a state agency. In our survey of P&As, we found that only 11 states track restraint use in private psychiatric facilities.

JCAHO does not require hospitals to report sentinel events but encourages voluntary reporting. JCAHO reports that since it adopted its current policy on voluntary reporting of sentinel events in 1996, it has received reports of 24 restraint-related deaths in facilities it accredits. It published a Sentinel Event Alert based on these reports in November 1998 with a summary of the analyses of 20 restraint-related deaths from the sentinel event database. However, voluntary reporting to JCAHO is not complete. JCAHO found out about at least three deaths that had not been reported to it as a result of the Hartford Courant's report of deaths. Even if a sentinel event is not reported to it, JCAHO expects hospitals to conduct an internal review to determine how to avoid similar incidents.

Deaths Reported to Protection and Advocacy Agencies Understate the Problem

Because reporting is so piecemeal, the exact number of deaths in which restraint or seclusion was a factor is not known. We contacted the P&As for each state and the District of Columbia and asked them to identify people in treatment settings who died in fiscal year 1998 and for whom restraint or seclusion was a factor in their death. The P&As identified 24, but this number is likely to be an understatement, because many states do not require all or some of their facilities to report such incidents to a P&A.

The Congress has required the states to establish or designate P&As to protect people with mental illness or mental retardation from abuse and neglect by providers when state oversight is insufficient. This system began for individuals with

[3] *Federal Register*, Vol. 64, No. 127, 36070 (July 2, 1999).

mental retardation in 1975, following the discovery of severe patient neglect and abuse at a state-run facility for the mentally retarded in New York, and it was expanded to individuals with mental illness when the Congress learned of similarly appalling conditions in psychiatric hospitals in 1985. P&As are charged with investigating reports of abuse, neglect, and other violations of the rights of mentally disabled individuals in institutional care and with pursuing legal and administrative remedies. In most states, the same P&A agency serves both individuals with mental illness and those with mental retardation.

Despite their charge, P&A representatives told us that they do not learn of all the deaths that may be related to restraint or seclusion. Only 15 of the 51 P&As receive any kind of systematic reports of deaths from their states or psychiatric facilities. Of the 15, 9 receive death reports for state facilities only and not for private facilities.

Because of the lack of reporting requirements in so many states, most P&As learn about deaths through complaints from family, patients, and staff as well as from on-site monitoring. Even with these ad hoc methods, only 22 of these agencies had deaths reported to them in 1998 by any means. Of the deaths reported to the P&As in fiscal year 1998, just 5 states accounted for more two-thirds, and no deaths were reported to the P&As in 28 states.

P&As investigated only about 30 percent of the deaths they learned about. One agency in New York accounted for almost one-third of all the death investigations, while four other agencies investigated 107 deaths combined. P&A officials also told us that their ability to conduct investigations is hindered by limited resources and obstacles in obtaining records, particularly the incident reports and medical records that enable them to thoroughly investigate deaths. According to some P&A officials, health facilities often claim that these records are part of the peer review process—a process in which medical professionals in a facility review incidents. While P&As may have legal rights to review the records, a P&A may have to litigate to obtain them. This can use up its limited resources and delay needed investigations.

Information may be even more difficult to obtain from private facilities. Obtaining information from private facilities is becoming increasingly important as more individuals with mental illness are being served in them. While many state agencies may gather data from their own facilities, private psychiatric facilities are usually not required to report data to either the state or the P&As.

Policies Governing Restraint and Seclusion Vary Among Federal Programs, States, and Facilities

Policies covering restraint and seclusion vary among federal programs, states, and types of facilities. The federal government regulates the use of restraint and seclusion in nursing homes and ICF–MRs but until recently had no such regulations for hospitals, including psychiatric hospitals. In August 1999, HCFA incorporated patients' rights provisions that address restraint and seclusion into the hospital conditions of participation. These requirements establish the right to freedom from restraint or seclusion for purposes of coercion, discipline, or staff convenience. Restraint and seclusion can be used only for medical and surgical care and in emergencies to ensure a patient's physical safety and only after less restrictive interventions have been found ineffective to protect a patient or others from harm. However, current regulations do not protect patients receiving psychiatric care in non hospital settings such as residential treatment centers for children and group homes.

The states have varying degrees of regulation and oversight for restraint and seclusion. Some states have different standards for their state-run facilities and private providers. In addition, private psychiatric hospitals are frequently not subject to the same degree of oversight as the state-run facilities. Some states like New York and Pennsylvania that have extensive regulation of their public hospitals have not imposed the same requirements on privately operated facilities—even though they may be state-licensed or may be receiving federal or state funding.

HFCA relies primarily on the accreditation process to determine whether privately operated facilities such as hospitals are eligible to participate in Medicare and Medicaid. We found that representatives of health care providers and family advocates differed on whether the accreditation process alone is sufficient to protect patients from improper restraint and seclusion. JCAHO, which accredits about 80 percent of the hospitals that participate in Medicare, applies the same standards on restraint and seclusion in hospitals as it applies in nonhospital behavioral health care treatment facilities. In JCAHO's accreditation survey, the surveyors review records to determine whether restraint or seclusion is being used and documented according to facility policy. It does not set standards regarding training and clinical issues such as the frequency of monitoring and the types of restraint that are preferable.

Representatives of health care providers told us that they believe that the accreditation process is the most appropriate way to ensure that patients are protected from improper restraint and seclusion. They said that a voluntary review process allows the facility to address any systemic clinical problems and develop plans for improving quality. In contrast, many advocates are concerned that the accreditation process is not sufficient to establish consistent patient protection because it stresses compliance with each facility's own policies. JCAHO surveyors tour facilities and talk with patients and staff to better understand their care issues. However, advocates have noted that the process emphasizes paperwork reviews that can miss ongoing problems with the quality of care. The HHS Inspector General recently reported that the accreditation process plays a positive role in the improvement of quality but cannot be relied upon alone to ensure patient protection.[4]

Some of the advocates and state administrators we interviewed believe that the most effective monitoring system involves a combination of internal and external oversight. External monitors complement internal quality control systems by providing an independent perspective. In some cases, courts have appointed independent monitors to ensure compliance with specific requirements and the safeguarding of basic patient rights in facilities that have had serious problems. In addition to using accreditation or state licensing surveyors and P&As, some states allow trained lay monitors to visit mental health facilities unannounced and assess environmental conditions. In Delaware, for example, if a monitor reports a concern about conditions in the state psychiatric hospital, the facility must respond within 10 days. Because staff at the facilities know that management reviews the reports and acts on them, they sometimes inform monitors about concerns that affect patient care, such as low staffing levels.

Restraint and Seclusion Can Be Reduced Through Regulation, Reporting, Staffing, and Training

Several states have successfully lowered the use of restraint and seclusion in their public psychiatric health systems and put reporting requirements into place. Restraint and seclusion rates in Pennsylvania's state hospital system declined by more than 90 percent between 1993 and 1999. In Delaware, the state's ICF–MR introduced an initiative that reduced its restraint rate by 81 percent between 1994 and 1997. Typically, successful strategies to reduce restraint and seclusion rates have similar components: a defined set of principles and policies to clearly outline when these measures can be used, strong management commitment, the reporting of restraint and seclusion use, oversight and monitoring, and intensive staff training in behavioral assessment, nonviolent intervention, and using safe restraint techniques as a last resort.

Delaware, Massachusetts, New York, and Pennsylvania have adopted strategies to reduce restraint use in their public mental health or mental retardation service systems. The officials we met with at the state health departments indicated that the primary element for their success in reducing restraint use is management commitment. Management philosophy, not the severity of patients' mental disability, was the most important factor in determining restraint use among different state hospitals, according to a 1994 study conducted by the New York Commission on Quality of Care.[5] Management can take responsibility for shaping the overall culture in which restraint and seclusion are considered either routine practice or last-resort measures. An integral part of this commitment is a clearly delineated set of policies and procedures governing the use of restraint and seclusion for staff to follow.

For example, Pennsylvania, which administers a system of 10 facilities with more than 3,000 residential psychiatric patients, was able to reduce both restraint and seclusion hours by more than 90 percent between 1993 and 1999. The state mental health leadership accomplished this by first emphasizing to all hospital administrators and staff that restraint and seclusion are not treatment but, rather, represent an emergency response to a treatment failure that resulted in a patient's loss of control. The Department of Mental Health issued policies that specified that restraint or seclusion can be used only after all other interventions have failed and only when there is imminent danger of the patient or others coming to physical harm. A physician's on-site assessment is required within 30 minutes. According to state officials, there was some initial opposition to these policies within the facilities, but the department's emphasis on maintaining adequate staffing and improving crisis man-

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[4] HHS, Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability* (Washington, D.C.: July 20, 1999).

[5] New York State Commission on Quality of Care for the Mentally Disabled, *Restraint and Seclusion Practices in New York State Psychiatric Facilities* (Albany, N.Y.: 1994).

agement training allowed it to gain the support of psychiatrists and direct care workers.

Reporting requirements are central to lowering restraint use and improving patient safety. Officials in New York and Pennsylvania stated that accurate and complete reporting allows hospital administrators to compare their facilities with others. This creates an incentive for administrators with high restraint rates to find ways to reduce them so that they are more in line with those of their peers. A 1999 survey by the National Association of State Mental Health Program Directors indicates that 18 states currently collect data on restraint or seclusion in their public hospitals.

In addition to tracking restraint rates, the reporting of deaths and sentinel events to an independent agency can help improve patient safety. New York is unique among the states in its longstanding, comprehensive reporting requirement. All licensed hospitals that provide inpatient psychiatric care must report all deaths to the Commission on Quality of Care as well as to the relevant state agency and must indicate whether a patient was secluded or restrained within the 24 hours before his or her death. Mandatory reporting and investigation allow an independent entity to analyze events at multiple facilities. Because the commission and other agencies review information from the entire state, they can determine whether incidents that appear to be isolated events from the perspective of individual providers are actually part of a pattern. For example, comprehensive incident reviews led to the discovery that the use of two authorized restraints—the prone wrap-up, which immobilizes a person in a face-down position, and a towel to prevent biting or spitting—were associated with several injuries and deaths throughout the state.[6] As a result of these analyses, these two types of restraint were banned.

Clinicians, advocates, labor unions representing direct-care mental health workers, program administrators, and providers consistently stress that training and adequate staff-to-patient ratios are essential to safely minimize the use of restraint and seclusion. Nurses and direct-care staff need to have effective alternative methods for handling potentially violent patients if they are to reduce their use of restraint and seclusion. In the states we visited, training programs that address how to handle potentially violent or aggressive patients were an integral part of the effort to safely reduce reliance on restraint and seclusion. In HCFA's interim final rule implementing new general and psychiatric hospital conditions of participation in Medicare and Medicaid, the agency has added requirements that hospitals train their staff in alternative techniques to lessen the use restraint and seclusion, but these requirements do not extend to other facility types.

Delaware, Massachusetts, New York, and Pennsylvania have initiated training programs that emphasize crisis prevention. The goal of training is to provide staff with the skills to assess potentially violent situations and intervene early to help patients regain control. State officials as well as labor union representatives stressed that direct-care staff must be trained in alternative techniques if a facility is serious about reducing restraint and seclusion.

Delaware ICF–MR officials told us that patient and staff injuries decreased after staff had been trained in alternative ways of managing patient behavior. According to a patient advocate, Delaware's emphasis on reducing restraint rates was precipitated by a 1994 restraint-related death in the state ICF–MR. Following the implementation of a new training program that emphasized patient-centered training in crisis prevention and new management priorities, this facility reduced the number of emergency restrictive procedures by 81 percent between 1994 and 1997, with the number of procedures per resident falling from 1.38 to 0.29 during that time. Along with this reduction in restraint, the number of major injuries to residents fell by 78 percent and resident behavior improved. A psychologist from Delaware's ICF–MR noted that once staff have experienced success in calming a patient through alternative means when they would have otherwise used restraint, the new techniques become "self-reinforcing" because staff prefer to use the less drastic measures.

The mental health program officials we met with indicated that training in alternatives to restraint and seclusion and maintaining adequate staff levels are costly but that they can save money in the long run by creating a safer treatment and work environment. Data from state hospitals in New York indicated that usually facilities with higher restraint and seclusion rates had higher rates of staff injury and lost staff time. A New York official noted that many of the injuries classified

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[6] Certain hospitals have authorized the use of a towel as a precaution against biting and spitting during take-down and the use of restraints to protect staff against possible infection. The commission indicated that no objects should ever be placed over or near a patient's face because of the danger of asphyxiation, and it recommended that staff wear gloves and masks and, if necessary, wrap the patient in a "calming blanket" to provide the staff with a safe barrier.

as assaults actually take place during restraint and seclusion procedures. According to state officials, staff training has been found to save the state money by directly reducing the frequency of restraint-related staff injuries, which represent the costs of sick leave and overtime payments for staff to cover the shifts.

Concluding Observations

The experience of several states shows that the use of restraint and seclusion can be reduced and that patients and staff are safer as a result. Successful strategies include ensuring management commitment, providing clear guidelines and a comprehensive reporting requirement, maintaining adequate staffing levels, and providing training.

The federal government has a major role in funding services for people with mental illness and mental retardation. HCFA has taken positive steps to ensure better reporting and patient protection through its new hospital conditions of participation. However, we believe that more can be done to ensure that Medicare and Medicaid patients with mental illness or mental retardation are protected from improper seclusion and restraint and from injuries and deaths. In our recently released report, we recommended that HCFA should develop consistent policies to ensure that mentally ill or mentally retarded individuals are given protection against inappropriate restraint and seclusion in every treatment setting that Medicare and Medicaid fund. We recommended that the use of restraint and seclusion and any associated injuries or deaths be reported to the state licensing body and state P&A. In addition, we recommended that facility staff regularly receive training in safe methods to handle agitated individuals, including training in alternatives to using restraint and seclusion. HCFA officials said that they would review and consider implementing each of our recommendations in the near future.

Mr. Chairman, this concludes my statement. I will be happy to answer your questions.

PREPARED STATEMENT OF HON. CHRISTOPHER J. DODD

Thank you Chairman Roth and Senator Moynihan for convening this morning's hearing. Obviously, this is a sad moment for all of us. With the loss of our good friend and esteemed member of this panel, Senator John Chafee, the Nation has lost a great man and a devoted public servant. During his 23 year tenure in the Senate, John championed the causes of many of our Nation's forgotten and needy. I have little doubt that John would support the effort that Senator Lieberman and I have undertaken to curb the deadly misuse of restraints and seclusion on individuals with mental illnesses.

Mr. Chairman, Members of the Committee, 12 years ago this panel passed landmark legislation that strictly regulated the use of restraints and seclusion on nursing home patients. Now, we are faced with the opportunity to do the same for individuals with mental illnesses. As pointed out by the Hartford Courant and the GAO when investigating the use of seclusion and restraint, more than 150 deaths have been found directly attributable to the misuse of restraint and seclusion over the past decade. Equally tragic, however, are the nameless and faceless individuals who are killed or injured by abusive restraint and seclusion practices that we never learn of. In fact, both the Hartford Courant and the GAO determined that there is no way presently to determine exactly how many people with mental illnesses are killed or injured due to the misuse of restraints or seclusion. The Harvard Center for Risk Analysis estimates that as many as 150 deaths per year may be caused by restraints or seclusion. The deaths we are aware of are most likely just the tip of the iceberg. This is a tragedy, with your help, we are going to end these abusive practices. We did it for patients in nursing homes and we should do it for individuals with mental illnesses.

The bills that Senator Lieberman and I have introduced differ in various respects. But, taken together, they share a common core: They create tough new limits on the use of potentially lethal restraints—be they physical or chemical in nature; they set rules for training mental health care workers; and they increase the likelihood that a wrongful death of a mental health patient will be investigated and prosecuted—not ignored. Our legislation simply seeks to put an end to a shameful record of neglect and abuse of some our nation's most vulnerable and least cared for individuals.

The provision that this committee passed a dozen years ago that helped stop the negligent and abusive treatment of nursing home patients was a simple measure that established strict guidelines on how and when restraints and seclusion could

be used. Both mine and Senator Lieberman's legislation start by extending this same protection to the mentally ill.

In particular, our bills, taken together, will:

First, set standards for restraint and seclusion use.

- Physical and chemical restraints may only be used when a patient poses an imminent risk of physical harm to himself or others. No longer will the use of restraints or seclusion for reasons of discipline, punishment, or convenience be tolerated. This is accomplished by extending to the mental health population the existing standard enacted by this committee as part of the 1997 Omnibus Budget and Reconciliation Act that has already proven effective in reducing the use of restraints in nursing homes.

Second, help ensure that providers who violate the rights of the mentally ill will be held accountable.

- Our bills will require facilities serving the mentally ill to report all deaths as a result of seclusion or restraint to an appropriate agency—as determined by the Secretary of Health and Human Services—for oversight and investigation.
- They will also grant the Secretary of Health and Human Services the authority to end any federal funding for mental health care providers that violate the protections the bill establishes.

Third, we will ensure adequate staff training and staff levels.

- Mental health aides are consistently the least-trained and lowest-paid workers in the health care field. Presently, there are no uniform or minimum federal training standards for mental health care workers. In many states, there are stricter standards for the care of pets than for the care of these vulnerable children and adults.
- Our legislation will help ensure adequate staffing levels and appropriate training for staff of facilities that serve the mentally ill. Specifically, our legislation requires the Secretary of Health and Human Services to set regulations requiring mental heath providers to adequately train their staff in the correct application of restraints and their alternatives and to ensure that appropriate staffing levels are maintained.

S. 750, The Compassionate Care Act was reported favorably out of the Health and Education Committee as part of the Substance and Mental Health Services Administration (SAMHSA) reauthorization this past July by a vote of 17 to 1. I am hopeful that this legislation will pass the Full Senate before adjournment. I hope that the Members of this Committee will also look favorably on the companion legislation pending before you.

We are here today to talk about something that we all can do that will save lives. Senator Lieberman and I implore this Committee and the entire Senate, to do for individuals with mental illnesses what we have already done for our elderly living in nursing homes. I know of no Senator that believes that facilities that serve the mentally ill should not be held to the same standards of care and safety that nursing homes adhere to. Those with mental illnesses deserve nothing less.

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Day Three ▪
Day Four ▪
Day Five ▪
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Two Connecticut Deaths, Two Questionable Investigations

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A Nationwide Pattern of Death

By ERIC M. WEISS
With reporting by Dave Altimari, Dwight F. Blint and Kathleen Megan
This story ran in The Courant on October 11, 1998

Roshelle Clayborne pleaded for her life.

Slammed face-down on the floor, Clayborne's arms were yanked across her chest, her wrists gripped from behind by a mental health aide.

I can't breathe, the 16-year-old gasped.

Her last words were ignored.

A syringe delivered 50 milligrams of Thorazine into her body and, with eight staffers watching, Clayborne became, suddenly, still. Blood trickled from the corner of her mouth as she lost control of her bodily functions.

Her limp body was rolled into a blanket and dumped in an 8-by-10-foot room used to seclude dangerous patients at the Laurel Ridge Residential Treatment Center in San Antonio, Texas.

The door clicked behind her.

No one watched her die.

For The Record: 11 Months, 23 Dead

Click on picture to see profiles.

But Roshelle Clayborne is not alone. Across the country, hundreds of patients have died after being restrained in psychiatric and mental retardation facilities, many of them in strikingly similar circumstances, a Courant investigation has found.

They died pinned down on the floor by hospital aides until the breath of life was crushed from their lungs. They died strapped to beds and chairs with thick leather belts, ignored until they strangled or their hearts gave out.

Those who died were disproportionately young. They entered our health care system as troubled children. They left in coffins.

All of them died at the hands of those who are supposed to protect, in places intended to give sanctuary.

If Roshelle Clayborne's death last summer was not an isolated incident, neither were the recent deaths of Connecticut's Andrew McClain or Robert Rollins.

A **50-state survey by The Courant**, the first of its kind ever conducted, has confirmed 142 deaths during or shortly after restraint or seclusion in the past decade. The survey focused on mental health and mental retardation facilities and group homes nationwide.

But because many of these cases go unreported, the actual number of deaths during or after restraint is many times higher.

Between 50 and 150 such deaths occur every year across the country, according to a statistical estimate commissioned by The Courant and conducted by a research specialist at the Harvard Center for Risk Analysis.

That's one to three deaths every week, 500 to 1,500 in the past decade, the study shows.

"It's going on all around the country," said Dr. Jack Zusman, a psychiatrist and author of a book on restraint policy.

The nationwide trail of death leads from a 6-year-old boy in California to a 45-year-old mother of four in Utah, from a private treatment center in the deserts of Arizona to a public psychiatric hospital in the pastures of Wisconsin.

In some cases, patients died in ways and for reasons that defy common sense: a towel wrapped around the mouth of a 16-year-old boy; a 15-year-old girl wrestled to the ground after she wouldn't give up a family photograph.

Many of the actions would land a parent in jail, yet staffers and facilities were rarely punished.

"I raised my child for 17 years and I never had to restrain her, so I don't know what gave them the right to do it," said Barbara Young, whose daughter Kelly died in the Brisbane Child Treatment Center in New Jersey.

The pattern revealed by The Courant has gone either unobserved or willfully ignored by regulators, by health officials, by the legal system.

The federal government -- which closely monitors the size of eggs -- does not collect data on how many patients are killed by a procedure that is used every day in psychiatric and mental retardation facilities across the country.

Neither do state regulators, academics or accreditation agencies.

"Right now we don't have those numbers," said Ken August of the California Department of Health Services, "and we don't have a way to get at them."

The regulators don't ask, and the hospitals don't tell.

As more patients with mental disabilities are moved from public institutions into smaller, mostly private facilities, the need for stronger oversight and uniform standards is greater than ever.

"Patients increasingly are not in hospitals but in contract facilities where no one has the vaguest idea of what is going on," said Dr. E. Fuller Torrey, a nationally prominent psychiatrist, author and critic of the mental health care system.

Because nobody is tracking these tragedies, many restraint-related deaths go unreported not only to the government, but sometimes to the families themselves.

"There is always some reticence on reporting problems because of the litigious nature of society," acknowledged Dr. Donald M. Nielsen, a senior vice president of the American Hospital Association. "I think the question is not one of reporting, but making sure there are systems in place to prevent these deaths."

Typically, though, hospitals dismiss restraint-related deaths as unfortunate flukes, not as a systemic issue. After all, they say, these patients are troubled, ill and sometimes violent.

The facility where Roshelle Clayborne died insists her death had nothing to do with the restraint. Officials there say it was a heart condition that killed the 16-year-old on Aug. 18, 1997.

Bexar County Medical Examiner Vincent DiMaio ruled that Clayborne died of natural causes, saying that restraint use was a separate "clinical issue."

But that, too, is typical in restraint cases. Medical examiners rarely connect the circumstances of the restraint to the physical cause of death, making these cases impossible to track through death certificates.

The explanations don't wash with Clayborne's grandmother.

"I'll picture her lying on that floor until the day I die," Charlene Miles said. "Roshelle had her share of problems, but good God, no one deserves to die like that."

With nobody tracking, nobody telling, nobody watching, the same deadly errors are allowed to occur again and again.

Of the 142 restraint-related deaths confirmed by The Courant's investigation:

Twenty-three people died after being restrained in face-down floor holds.

Another 20 died after they were tied up in leather wrist and ankle cuffs or vests, and ignored for hours.

Causes of death could be confirmed in 125 cases. Of those patients, 33 percent died of asphyxia, another 26 percent died of cardiac-related causes.

Ages could be confirmed in 114 cases. More than 26 percent of those were children – nearly twice the proportion they constitute in mental health institutions.

Many of the victims were so mentally or physically impaired they could not fend for themselves. Others had to be restrained after they erupted violently, without warning and for little reason.

Caring for these patients is a difficult and dangerous job, even for the best-trained workers. Staffers can suddenly find themselves the target of a thrown chair, a punch, a bite from an HIV-positive patient.

Yet the great tragedy is that many of the deaths could have been prevented by setting standards that are neither costly nor difficult: better training in restraint use, constant or frequent monitoring of

patients in restraints; the banning of dangerous techniques such as face-down floor holds; CPR training for all direct-care workers.

"When you look at the statistics and realize there's a pattern, you need to start finding out why," said Dr. Rod Munoz, president of the American Psychiatric Association, when told of The Courant's findings. "We have to take action."

Mental health providers, who treat more than 9 million patients a year at an annual cost of more than $30 billion, judge themselves by the humanity of their care. So the misuse of restraints -- and the contributing factors, such as poor training and staffing -- offers a disturbing window into the overall quality of the nation's mental health system.

For their part, health care officials say restraints are used less frequently and more compassionately than ever before.

"When it comes to restraints, the public has a picture of medieval things, chains and dungeons," said Dr. Kenneth Marcus, psychiatrist in chief at Connecticut Valley Hospital in Middletown. "But it really isn't. Restraints are used to physically stabilize patients, to prevent them from being assaultive or hurting themselves."

But in case after case reviewed by The Courant, court and medical documents show that restraints are still used far too often and for all the wrong reasons: for discipline, for punishment, for the convenience of staff.

"As a nation we get all up in arms reading about human rights issues on the other side of the world, but there are some basic human rights issues that need attention right here at our back door," said Jean Allen, the adoptive mother of Tristan Sovern, a North Carolina teen who died after aides wrapped a towel and bed sheet around his head.

Others have a simple explanation for the lack of attention paid to deaths in mental health facilities.

"These are the most devalued, disenfranchised people that you can imagine," said Ron Honberg, director of legal affairs for the National Alliance of the Mentally Ill. "They are so out of sight, so out of mind, so devoid of rights, really. Who cares about them anyway?"

Few seemed to care much about Roshelle Clayborne at Laurel Ridge, where she was known as a "hell raiser."

But Clayborne had made one close friendship -- with her roommate, Lisa Allen. Allen remembers showing Clayborne how to throw a football during afternoon recess on that summer afternoon in 1997.

"She just couldn't seem to get it right and she was getting more and more frustrated. But I told her it was OK, we'd try again tomorrow," said Allen, who has since rejoined her family in Indiana.

Within three hours, Clayborne was dead.

She had attacked staff members with pencils. And staffers had a routine for hell raisers.

"This is the way we do it with Roshelle," a worker later told state regulators. "Boom, boom, boom: [medications] and restraints and seclusion."

After she was restrained, Roshelle Clayborne lay in her own waste and vomit for five minutes before anyone noticed she hadn't

moved. Three staffers tried in vain to find a pulse. Two went looking for a ventilation mask and oxygen bag, emergency equipment they never found.

During all this time, no one started CPR.

"It wouldn't have worked anyway," Vanessa Lewis, the licensed vocational nurse on duty, later declared to state regulators.

By the time a registered nurse arrived and began CPR, it was too late. Clayborne never revived.

In their final report on Clayborne's death, Texas state regulators cited Laurel Ridge for five serious violations and found staff failed to protect her health and safety during the restraint. They recommended Laurel Ridge be closed.

Instead, the state placed Laurel Ridge on a one-year probation in February and the center remains open for business. In a prepared statement, Laurel Ridge said it has complied with the state's concerns -- and it pointed out the difficulty in treating someone with Clayborne's background.

"Roshelle Clayborne, a ward of the state, had a very troubled and extensive psychiatric history, which is why Laurel Ridge was chosen to treat her," the statement said. "Roshelle's death was a tragic event and we empathize with the family."

With no criminal prosecution and little regulatory action, the Clayborne family is now suing in civil court. The Austin chapter of the NAACP and the private watchdog group Citizens Human Rights Commission of Texas are asking for a federal civil rights investigation into the death of Clayborne.

Medications and restraint and seclusion.

Clayborne's friend, Lisa Allen, knew the routine well, too.

For six years, Allen, now 18, lived in mental health facilities in Indiana and Texas, where her explosive personality would often boil over and land her in trouble.

By her own estimate, Allen was restrained "thousands" of times and she bears the scars to prove it: a mark on her knee from a rug burn when she was restrained on a carpet; the loss of part of a birthmark on her forehead when she was slammed against a concrete wall.

Exactly two weeks after Roshelle Clayborne's death, Lisa Allen found herself in the same position as her friend.

The same aide had pinned her arms across her chest. Thorazine was pumped into her system. She was deposited in the seclusion room.

"It felt like my lungs were being squished together," Allen said.

But Lisa Allen was one of the lucky ones.

She survived.

Additional research was contributed by Sandy Mehlhorn, Jerry LePore and John Springer

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A Different Kind Of Restraint: Understanding

A Vicious Cycle Of Stifling Anger

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Why They Die

Little Training, Few Standards, Poor Staffing Put Lives At Risk

By KATHLEEN MEGAN and DWIGHT F. BLINT
With reporting by Dave Altimari
This story ran in The Courant on October 12, 1998

She was a 15-year-old patient, alone in a new and frightening place, clutching a comforting picture from home.

He was a 200-pound mental health aide bent on enforcing the rules, and the rules said no pictures. She defied him; the dispute escalated.

And for that, Edith Campos died. She was crushed face down on the floor in a "therapeutic hold" applied by a man twice her size.

Shy and well-behaved as a girl growing up in Southern California, Edith had problems as a teen. She ran away, took drugs, hung with the wrong crowd. Her family hoped treatment at the Desert Hills psychiatric center in Tucson, Ariz., would help.

WESTERN STATE HOSPITAL, a 375-bed facility in Staunton, Va., is part of a federal investigation into the quality of mental health care throughout Virginia. Here, a patient in Western's forensic unit, naps in his room.

But Edith Campos died -- as did Andrew McClain and Roshelle Clayborne and countless others -- when a trivial transgression spiraled into violence. Too often, it's a reaction built right into our system that cares for people with psychiatric problems and mental retardation.

The people who make and execute the critical decisions to use physical force or strap a patient to a bed or chair are often aides, the least-trained and lowest-paid workers in the field.

They must make instantaneous decisions affecting patients' physical and psychological well-being against a backdrop of staffing cuts that result more in crowd control than in patient therapy.

"I can't understand why patients don't die more often with all the things that happen on a daily basis," said Wesley B. Crenshaw, a psychologist who has conducted one of the few national surveys on restraint use.

"You have people who are 'cowboying' it," Crenshaw said, "people who really want to get in there and show they're the boss."

Yet only three states -- California, Colorado and Kansas -- actively license aides in psychiatric facilities. Licensing of aides is nearly non-existent in the mental retardation field as well, although a handful of states do certify aides.

So, while individual states and facilities may set their own standards, there is no uniform, minimum training for psychiatric or mental retardation aides nationwide -- even in life-saving techniques such as CPR.

In the Edith Campos case, aide Daniel Thomas Walsh successfully fought negligent homicide charges by arguing he had followed hospital guidelines. And the guidelines didn't say he needed to watch Edith's face for signs of distress, the judge found.

"It was a tragedy that this girl died in our care," said Kirke Cooper, director of business development for Desert Hills. "But I don't feel there was any wrongdoing on the part of our staff. They are all well-trained in physical control and seclusion."

Done correctly, a restraint can protect a patient and worker from harm. Done under the right circumstances, patients say, it can be beneficial.

Yet too often, it is done badly and for the wrong reasons. Nowhere is this tragedy more apparent than in the deaths of children.

A Courant investigation has found more than 26 percent of restraint-related deaths over the past decade involved patients 17 and under. Yet children make up less than 15 percent of the population in psychiatric and mental retardation facilities, according to federal statistics.

The death rate should come as no surprise.

"You can't believe how many times a kid gets slammed into restraints because an argument will ensue after calling a staff member a name," said Wanda Mohr, director of psychiatric mental health nursing at the University of Pennsylvania.

She and other analysts say children disproportionately bear the brunt of the misuse and overuse of restraints. A 1995 New York study, for instance, found children almost twice as likely as adults to be restrained.

"It's socially acceptable to spank and punish children," said Mohr, reflecting the responses of other experts who say our culture tolerates a physical response to unruly children.

Yet children are both a vulnerable and challenging population.

Firm diagnoses often cannot be made until late adolescence or early adulthood, so providers are less sure how to treat children. And many troubled children enter the mental health system with histories of physical or sexual abuse -- so even the threat of physical force can be traumatizing.

For their part, many patients say improper or frequent use of restraints hurts their recovery and defeats the very reason they were admitted. In interviews with more than a dozen children and adults, The Courant's investigation found these patients were left confused, angry and afraid.

They rarely felt better.

Researchers are finding the same. In a 1994 New York study, 94 percent of patients restrained or placed in seclusion had at least one complaint about the process. Half complained of unnecessary

force, 40 percent cited psychological abuse.

In a study published this year, Mohr interviewed children after their hospital stays and found many were further traumatized when they were restrained or secluded – or even watching others undergo the procedure. Usually, she found, children saw such treatment as punishment.

The leader of the nation's psychiatric association acknowledged the problem.

"It must be especially frightening for a child," said Dr. Rod Munoz, president of the American Psychiatric Association. "It's a struggle of wills where the most powerful win."

And troubled children are the ones who lose.

Elaina Huckin, 17, of Granby, Conn., is still so disturbed by a restraint five years ago that she can barely speak about it. She was put in a "body bag," a sort of neck-to-toe straitjacket.

"They tie you in it. They pull it tighter and tighter. I couldn't move to breathe," Huckin said. "I was screaming and pleading, 'Somebody, please, somebody take me out.'

"It made you so much more suicidal," she said.

As mental health aides take this step that can do such physical and psychological harm, they are poorly monitored much of the time.

ELAINA HUCKIN, 17, still has nightmares about being restrained in a body bag – a sort of neck-to-toe straitjacket – five years ago. Huckin was last hospitalized in February 1996. She posed for this photo with her mother, Karen Huckin, at their home in Granby.

Although most institutions require a supervisor to oversee a physical restraint, The Courant found such rules are often ignored.

When 11-year-old Andrew McClain was restrained last March at Elmcrest psychiatric hospital in Portland, Conn., the duty nurse sat nearby eating breakfast. She ignored the initial cries of distress from Andrew, whose chest was crushed during the restraint.

The decision to strap a patient to a bed or chair, or cuff their hands, must be cleared by a doctor, according to many hospital and state policies. If a doctor is not available, efforts must be made to contact one as soon as possible.

But in more than a dozen cases reviewed by The Courant, patients were tied to their bed or chair for several hours at a time without regular review by a physician.

Mental health advocates say doctors must keep a closer eye on how long their patients are restrained.

"The ultimate responsibility falls to the doctors, who are supposedly the kings in these places," said Curtis L. Decker, executive director of an organization representing patient advocates nationwide. "They're in control and ought to exercise their authority."

Yet in certain facilities, physicians give staffers virtual carte blanche by issuing an order to restrain as needed.

"It's a go-ahead to slap restraints on a person without evaluating why the patient was acting up in the first place," said Dr. Moira Dolan, a medical consultant in Texas, where standing restraint orders are allowed in certain facilities. "There's no guidance on when to restrain someone."

Despite such responsibility, minimum hiring standards are few and pay is typically low for aides. A survey by The Courant last spring, for example, found aides were paid as little as $10 per hour in Connecticut.

When federal investigators began looking into the quality of care at Western State Hospital in Staunton, Va., last summer they found the $15,000 starting pay was less than what an employee could make at the nearby department store.

"When you can make $10 an hour working at the new Target," asked union representative Allen Layman, "what incentive is there to come here?"

Especially when the work can be demanding and dangerous.

For every 100 mental health aides, 26 injuries were reported in a three-state survey done in 1996. The injury rate was higher than what was found among workers in the lumber, construction and mining industries.

"Depending on the situation, it's scary, it's violent," said David Lucier, a veteran mental health worker at Natchaug Hospital in Mansfield, Conn. "Oftentimes, patients are kicking and punching and spitting and verbally abusive."

Over a 19-year career, Lucier said, he has developed communication skills that allow him to rarely touch patients. The skills described by Lucier are gained by training and by understanding the patients.

At some hospitals, though, staff are moved about like pawns in a chess game, leaving them little chance to know their patients.

To fill less-desirable shifts such as weekends, institutions use less-trained, part-time workers. When faced with wide fluctuations in the numbers of patients, they resort to shuffling workers from one unit to another.

A staff shortage landed aide Spero Parasco on Andrew McClain's unit March 22.

Parasco, who usually worked with adults, had never met Andrew before that morning at breakfast and had not read the child's medical chart. Indeed, Andrew's ward that Sunday was staffed largely with part-time workers.

So when Andrew defied Parasco's instructions to move to another table at breakfast, the dispute escalated into a "power struggle." Had workers known more about Andrew, had Parasco been better-versed in ways to calm him, the boy would not have died, a state investigation concluded.

Better staffing also reduces the risk of a restraint, like the face-down floor hold in which Andrew died.

The American Psychiatric Association recommends at least five people -- one for each limb, plus someone to watch -- be involved

in any physical restraint.

That would have been nearly impossible in Andrew's case. A total of five staffers were on duty in the unit that Sunday morning, overseeing 26 children. As it was, just two aides were involved in Andrew's restraint.

"A takedown requires four staff members and, with staff cuts being made at many institutions, they end up with only two people doing the work of four people," said Tom Gallagher of the Indiana Protection & Advocacy Services office. "That's when problems occur."

At least six of 23 recent deaths reviewed in depth by The Courant occurred during a restraint executed by only one or two people. Another six patients died in seclusion or mechanical restraints after being left, unmonitored, for several minutes or more.

"Hospitals have cut their staffing to a bare minimum," said Dr. David Fassler, a psychiatrist, author and chairman of the Council on Children, Adolescents and Their Families. The same fiscal pressures, he said, have led institutions to reduce training as well.

All this at a time when patients particularly need skilled help. As managed care limits access to hospitals, most analysts say patients are entering the system in more troubled conditions than ever before.

In the wards, staffers feel the pressure.

Pausing during a recent double shift at Western State Hospital in Virginia, a 375-bed facility for adults, nurse Judy Cook talked about the need to devote time to patients.

"Every time we've had a downsizing of staff we've had an increase in restraints and seclusions," said Cook, who has seen 23 years of trends at Western. "When you have more staff you can intercede better and you don't have to just place someone in restraints to calm them down."

But reducing the use of restraints requires a financial and philosophical commitment -- a commitment to use force only as a last resort, and only by well-trained staff who care about the patient.

Across the nation, the commitment is too often absent.

Last summer, a staff shortage at Western State forced nurses to call on security guards to help perform restraints. One guard, who didn't want his name used, showed little interest in the patients he might forcibly restrain.

Or much interest in doing it correctly.

"I didn't get hired," he said, "for all this bull-crap interacting with people or tackling psychotic patients."

Courant Staff Writer Eric M. Weiss contributed to this story.

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Attempt To Protect Falls Victim To Pressure

A Life Wanes In Restraint

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Patients suffer in a system without oversight

By ERIC M. WEISS and DAVE ALTIMARI
This story ran in The Courant on October 13, 1998

Had Gloria Huntley been able to move, had she not been bound to her bed with leather straps for days on end, perhaps she would have tried to draw the attention of the inspectors who were conducting a three-day tour of Central State Hospital.

Had she been able to move, had she not been pinned down by the wrists and ankles, she might have held up a sign, as she had done before when a visitor came through Ward 7. Her handwritten plea was simple: "Pray for me. I'm dying."

But the inspection team from the nation's leading accreditation agency never noticed Gloria Huntley before leaving the Petersburg, Va., psychiatric hospital.

The three inspectors from the Joint Commission on the Accreditation of Healthcare Organizations issued Central State a glowing report card -- 92 out of 100 points. They also bestowed the commission's highest ranking for patients' rights and care when they concluded their review on June 28, 1996.

The next day, Gloria Huntley died. She was 31.

Her heart, fatally weakened by the constant use of restraints, had inflamed to 1 1/2 times its normal size. In her last two months, she'd been restrained 558 hours -- the equivalent of 23 full days.

Nine months later, the Joint Commission gave Central State an even better score in a follow-up review -- even though Huntley's treatment would ultimately be labeled "inhumane" by the state of Virginia and condemned by the U.S. Justice Department.

"How could JCAHO give Central State the highest rating in human rights when they were killing people?" asked Val Marsh, director of the Virginia Alliance for the Mentally Ill.

The way the country's health care system works, how could it not?

The Courant's nationwide investigation of restraint-related deaths underscores just how faulty -- how rife with conflicts of interest, how self-protective, how ultimately ineffective -- the system of industry oversight and government regulation really is.

The health care industry is left to police itself, but often doesn't.

Time and again, The Courant found, when it comes to the quality and safety of patient care, the interests of the industry far outweigh the public interest.

"One reason you have overuse and misuse of restraints is because oversight is practically nonexistent," said Dr. E. Fuller Torrey, a nationally prominent psychiatrist and author of several books critical of the nation's mental health system. "And the health industry doesn't want oversight."

The chain of agencies, boards and advocates that is supposed to provide oversight -- the kind of oversight that might have prevented Huntley's death and hundreds like it -- often breaks down in multiple places.

But the heavy reliance on the Joint Commission -- an industry group that acts as the nation's de facto regulator -- lies at the core of the problem.

The federal government relies on the private nonprofit agency's seal of approval for a psychiatric hospital's acceptance into Medicare and Medicaid programs. And 43 states, including Connecticut, accept it as meeting most or all of its licensing requirements.

But the Joint Commission doesn't answer to Congress or the public. It answers to the health care industry.

The Joint Commission was founded in 1951 by hospital and medical organizations, whose members still dominate the commission's board of directors. The commission is funded by the same hospitals it inspects.

How tough are its inspections?

Of the more than 5,000 general and psychiatric hospitals that the Joint Commission inspected between 1995 and 1997, none lost its accreditation as a result of the agency's regular inspections

None.

When extraordinary circumstances arise -- a questionable death, for instance -- the Joint Commission may conduct additional inspections. Even then, less than 1 percent of facilities overall lost accreditation.

Central State was not among them.

Joint Commission officials are the first to say they are not regulators. Participation is voluntary, and 83 percent of hospitals inspected were found to have shortcomings that needed to be addressed.

"Joint Commission accreditation is intended to say to the patient: This is a place that does things well and is constantly working to improve things," said Dr. Paul M. Schyve, a psychiatrist and senior vice president of the Joint Commission.

If the industry is not adequately watching itself, neither is the government. The nation's top mental health official says he has little latitude when it comes to tougher regulation and oversight.

"Most rules governing health care have been left to the states," said Dr. Bernard S. Arons, director of the U.S. Center for Mental Health Services.

When it comes to mental retardation facilities, in fact, inspection is left largely to the states.

But their record is not much better.

The General Accounting Office, the investigative arm of Congress,

has found that state regulators are loath to punish state-run facilities.

In a study of state mental retardation centers, the GAO found "instances in which state surveyors were pressured by officials in their own and in other state agencies to overlook problems or downplay the seriousness of deficient care in large state institutions."

When state regulators do show up, their inspections are scheduled with such predictability that facilities can beef up staff, improve services and even apply fresh coats of paint. Often, only the new paint remains after the inspectors leave.

"These visits provide only a snapshot," said William J. Scanlon, director of health care studies for the GAO. "And it may be a doctored snapshot."

It is only when the system utterly collapses, as in the Gloria Huntley case, that the federal government intervenes to set rules for patient care.

Justice Department abuse investigators, who have authority to intercede when civil rights violations are suspected in publicly run facilities, often find these same facilities were recently given clean bills of health by licensing agencies or the Joint Commission.

"The use of restraints is clearly a very big problem and a very significant issue in nearly all of the institutions we investigate," said Robinsue Froehboese, the top abuse investigator at the Justice Department.

But with a staff of 22 attorneys, Froehboese's office can undertake only a handful of major investigations each year.

"Nineteenth-century England had a better oversight system than we have now," said Torrey, describing an English system that used full-time government inspectors to check every psychiatric facility without prior notice.

At Central State, the warning signs should have been apparent. But Joint Commission inspectors review just a sampling of patient records -- a sampling that may not include problem cases like Gloria Huntley's.

Anyone who did look at Huntley's records would have known her health was failing -- and that heavy use of restraints was a primary reason.

Two years before Huntley's death, a doctor warned officials at Central State that she would die if they didn't change her restraint plan.

"Staff members should watch their conscience, and those in charge must always remember that following physical struggle and emotional strain, the patient may die in restraints," stated the ominously titled "duty to warn" letter.

Even if the Joint Commission inspectors had missed Huntley in particular, there were other cases at Central State that should have raised red flags. One patient was restrained for 1,727 hours over an eight-month period, yet another for 720 hours over a four-month period, according to a U.S. Justice Department report.

So, in many respects, the investigation into Huntley's death is most remarkable in that it happened at all. When she died on June 29, 1996, the police were never called.

It took a hospital employee's anonymous call to a citizens watchdog group, days after Huntley's death, to tip off the outside world that she died while being restrained -- and not in her sleep as hospital officials told family members.

The Courant's investigation found at least six cases in which facilities, wary of lawsuits and negative publicity, tried to cover up or obscure the circumstances of a restraint-related death.

"It's sort of a secretive thing," said Dr. Rod Munoz, president of the American Psychiatric Association. "Every hospital tries to protect itself."

"The incentive is to settle with the family, fix it internally and move on," said Dr. Thomas Garthwaite, deputy undersecretary of health for the U.S. Department of Veterans Affairs.

Many states, including Connecticut, have laws that shield discussions among doctors that explore what went wrong. The laws are designed to promote candid discussions, but the solutions often don't leave the closed hospital conference room.

Garthwaite and other experts said hospitals need to share problems and solutions to prevent deadly errors from being repeated. Just a year ago, the VA began a comprehensive system to track all deaths and mistakes.

But a plan by the Joint Commission to do the same all across the nation has been stymied so far by the powerful American Hospital Association.

The AHA notified the Joint Commission in January that the proposal had created a "firestorm" among its members, who worried that they would have to turn over "self-incriminating" documents.

"We've tried to make the program workable, so people would not be afraid to report on a voluntary basis," said Dr. Donald M. Nielsen, a senior vice president of the American Hospital Association. He said the two groups agreed last month on some ground rules regarding the issue.

With the industry failing to monitor itself, with government regulators unwilling to challenge the industry, uncovering abuse is left to "protection and advocacy" agencies established by Congress in each state.

Despite $22 million in federal funding this year and broad authority to root out and litigate cases of abuse, even some advocates turn a blind eye to investigating deaths.

Desperate for help, Gloria Huntley turned to one of these organizations in her last months of life.

Not only was her complaint not investigated, but three weeks after her death Huntley was sent a letter saying the advocacy agency was dropping her case because it hadn't heard from her in 90 days.

The letter ends: "It was a pleasure working with you to resolve your complaint. I wish you the best of luck in your future endeavors."

Advocates say they have too little funding for their broad charge, and are fought every step of the way by hospitals and doctor groups. Scarce money and staffing are used just to secure basic information.

"It's a David and Goliath battle," said Curtis L. Decker, executive director of the group representing advocacy organizations

nationwide. "And Goliath is winning."

Hospitals see no need for drastic change, let alone more government intervention.

"Given the speed of government, it is often better to allow the private market to work issues out," said Nielsen of the AHA. "Joint Commission standards have been revised recently and are continually being improved."

Huntley's family might take issue with that assessment. They have filed a civil rights lawsuit in federal court seeking $2 million, and a wrongful death lawsuit in state court seeking $450,000.

"We knew from the get-go things weren't right when they told us she died in her sleep," said Paige Griggs, Huntley's sister-in-law.

"We thought she was being taken care of."

Courant Staff Writers Kathleen Megan and Dwight F. Blint contributed to this story.

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'People Die And Nothing Is Done'

By DAVE ALTIMARI
With reporting by Dwight F. Blint and John Springer
This story ran in The Courant on October 14, 1998

Sheriff Geno D'Angelo remembers the first time staffers at the Broome Developmental Center in Binghamton, N.Y., called his office for help last year.

A deer had been killed by a car in front of the center the evening of Nov. 24. The staff wanted it removed.

But no one from the state mental health facility had called D'Angelo four months earlier when William Roberts fell to his side, vomited and died after being restrained in a timeout room.

"I wonder how many of these deaths occur at that facility or others in this state that [police] never know about," said D'Angelo, who first learned about the death from a Courant reporter.

The Courant's investigation has found the nation's legal system falters time and again when it comes to restraint-related deaths. Just as the medical establishment fails to provide the kind of internal oversight that might prevent patients from dying, the legal system offers little hope for justice after they are dead.

ALVINA GAUTHIER and her family fought for a thorough investigation of the death of her daughter Sandra Gordon at the Rosewood Terrace Care Center in Salt Lake City in January. After an autopsy, the 45-year-old woman's death – originally deemed an accident – was ruled a homicide. The state of Utah eventually closed the facility. Please See Story.

Law enforcement officials, lawyers and mental health advocates say it isn't always easy, or appropriate, to place blame on the ill-trained mental health aides who typically execute restraints.

But without thorough investigation, the system too often fails to determine whether a death is a tragic accident or an act of criminal negligence. And whatever the circumstances, they say, patients' families are entitled to answers.

Yet the normal investigative process falls apart at each step, The Courant found.

Hospital workers cover up or obscure the circumstances of a death. Autopsies are not automatically performed. Police are not routinely summoned. Investigators often defer to the explanations offered by the institutions involved.

"It's easier to just say it was an accident and forget about it," said

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Shattering A 'Wall Of Silence'
A Daughter's Death
What We Found
Who Died And How
Restraint Use In Connecticut
Improper Technique
How The Courant Conducted Its Investigation
Common Terms

Michael Baden, a former New York state medical examiner who now serves on a state board that investigates deaths in institutions

Thus, few are ever punished. Prosecutors rarely pursue arrests in restraint deaths and, when they do, they typically accept plea bargains to minor charges.

"The way the system runs, people die and then nothing is done about it," said Raul Campos, whose 15-year-old daughter, Edith, died while restrained in a dispute over a photograph.

Hers was a rare case in which criminal charges were filed. But an Arizona judge found restraint deaths are such a "rarity" that it would have been unreasonable to expect the aide to notice Edith's distress. He tossed the case out.

Families of dead patients, angry with the lack of accountability in the criminal justice system, then turn to civil court where they face one last obstacle to justice: jurors who must place a monetary worth on people at the bottom rung of society.

"The law is not disability-friendly. If you're disabled or mentally retarded, you don't have any value," said Pennsylvania attorney Ron Costen, who represents families in abuse cases.

A former prosecutor, Costen is familiar with the flaws of criminal investigations into restraint deaths.

Among the common problems he cited: Scenes are not preserved because staff immediately clean up the room where the restraint occurred. Staffers develop a story emphasizing the patient's existing physical problems. And workers say they were just protecting themselves or others from harm, making it hard to prove criminal intent.

Others have found staffers reluctant to blow the whistle on colleagues.

"Despite the legal and ethical obligations to report and protect patients from abuse, a strong code of silence among direct care staff still exists," California investigators found last year after an investigation into restraint abuses at Napa State Hospital. Two people have died in restraint-related incidents at Napa State in the past six years.

The California report found a system rotting from within. It cited a survey in which two-thirds of psychiatric aides statewide believe there to be a "code of silence." Workers, the report said, consider themselves victims of a bad and abusive system.

In Pennsylvania, Costen intends to propose legislation to put the system, corporations and administrators, on trial -- and not simply the low-paid aides who work for them.

"We have to make it possible to attack the corporate structure and hold them accountable for criminal actions," Costen said. His proposal would carry no prison sentence, instead fining corporations or, in the worst cases, putting them out of business.

But punishment can only follow investigation. Police and prosecutors typically rely on medical examiners to trigger a criminal case by issuing a homicide ruling. The trigger is infrequently pulled.

In 23 recent deaths examined in depth by The Courant, only three were ruled homicides. In the other cases, including the Binghamton death, medical examiners ruled the deaths to be accidental or attributed them to the patient's existing medical problems.

Baden, of New York, said these rulings fail to take into account the full context in which the patient died.

"Positional asphyxiation has this very nice ring to it," said Baden, referring to a common cause of death in restraint cases. "Like maybe somebody did it to themselves instead of their chests being compressed."

Most medical examiners say they struggle with restraint cases, but ultimately cannot issue a homicide ruling if staffers are working within the scope of their jobs.

"It's difficult to say whether a hold put on a person has any role in their death unless it's clear-cut they were doing the hold wrong," said Vincent DiMaio, the Texas medical examiner who ruled that Roshelle Clayborne died of natural causes after being restrained in a San Antonio, Texas, facility.

Such clarity is nearly impossible. Across the country, The Courant has found, there are no clear, uniform standards on restraint use, and no minimum training standards for staffers.

So prosecution is rare, too.

"If a medical examiner rules a death accidental or by natural causes, it does make getting a criminal indictment more unlikely than not," said John Loughrey, a prosecutor in Monmouth County, N.J.

In June, Loughrey presented to a grand jury his case against two staffers at the Brisbane Child Treatment Center. Staffers said 17-year-old Kelly Young's hair was hiding her face during a restraint -- so they didn't notice that her lips were turning blue.

But the grand jury refused to issue indictments after hearing the death had been ruled accidental.

Faced with unfamiliar cases that are difficult to prove, most prosecutors simply shy away.

"There's enormous variability from state to state and even county to county on what the district attorney feels is a prosecutable offense," said Robinsue Froehboese, the U.S. Justice Department's top abuse investigator.

"Unfortunately," she said, "the jurisdictions that don't prosecute these cases far outweigh those who do."

Take the case of Melissa Neyman of Tacoma, Wash.

Gerald A. Horne, a Pierce County prosecutor, would not pursue charges in Neyman's death -- even though the state attorney general's office urged criminal prosecution against the owner and a worker at the Judith Young Adult Family Home.

Tied to her bed in a makeshift restraint on the night of July 23, 1997, Neyman managed to climb out a window before becoming entangled in the straps. The 19-year-old autistic woman had been dead six hours before workers finally noticed her -- hanging from the window about 3 or 4 feet from the ground.

"We don't charge persons who had goodwill and were doing the best job they could," Horne said.

"They didn't have any intent to hurt anybody."

But the staffer did put Neyman in a restraint without a physician's permission -- a direct violation of Washington state law. The same

staffer was not authorized to care for clients, did not check on Neyman for several hours, and lied to investigators about the circumstances of the death, the attorney general's office found.

When prosecutors do press charges or get indictments from grand juries, they rarely follow through and go to trial. More often they settle for a plea bargain that calls for no jail time.

Kimberlye Montgomery was originally charged with involuntary manslaughter and gross negligence, a felony with a maximum 15-year sentence, in the restraint death of 9-year-old Earl Smith in Detroit in November 1995.

Montgomery, a child-care worker at the Methodist Children's Home Society, sat on Smith and ignored his pleas for air because it was "typical of the ruses used by children to get themselves released from restraints," she said in a court deposition.

Montgomery eventually pleaded guilty to a misdemeanor and received an 18-month suspended sentence and 100 hours of community service.

Nancy Diehl, the Wayne County prosecutor who handled the Smith case, said she had little choice because many of the witnesses were other troubled children.

"We gave her a great plea because we felt we might have some problems convincing a jury of the original charge," Diehl said. "It certainly isn't easy because your witnesses are other young kids who have various problems. That's why they are in the home."

After navigating the criminal justice system and ending up empty-handed, the Smith family ended where many aggrieved families do -- in civil court. Detroit attorney Julie Gibson, who represented the Smiths, said her clients eventually realized it was best to settle the case.

In fact, few lawsuits involving restraint victims ever make it before a jury because they are settled quietly and out of court. In the mere handful of jury verdicts over the past two decades, awards typically fell under a half-million dollars, according to legal experts and a national tracking service.

When a case does go to trial, families face a final, common hurdle. Take the case of Roshelle Clayborne.

"What's the life of a poor, black, mentally ill girl who has been institutionalized for several years going to mean to a jury?" said Martin Cirkiel, the Texas attorney who represents Clayborne's family.

"I think the answer," Cirkiel said, "is not much."

Courant Staff Writers Colin Poitras, Kathleen Megan and Eric M. Weiss contributed to this story.

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Fighting In The Name Of Their Son

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From 'Enforcer' To Counselor

By ERIC M. WEISS
This story ran in The Courant on October 15, 1998

Will Overton used to be called "The Enforcer."

With 280 pounds of solid Tennessee muscle wrapped around a 6-foot-3 frame, the aide at the Harold W. Jordan Center was called in to help "shuffle" patients -- slamming them to the ground face-down if they acted up or disobeyed. And the 30 mentally retarded and mentally ill patients -- people accused of murder, rape and other crimes -- often disobeyed.

MIKE PIGNONE, an aide at the Harold W. Jordan Center, talks with a patient on the grounds of the Nashville facility. Recent changes at the center are the result of Tennessee's efforts to minimize the need to physically restrain patients. "If we could do it here, it can be done anywhere," said a Jordan Center administrator.

"I used to be a bad boy," said Robert Hall, a short, wiry patient with the energy of a wound rubber band. "I was shuffled about every day."

Not anymore. Behind the Nashville center's locked gates and razor wire a radical turnaround has occurred in the last year. Shuffling is now forbidden, staff has been increased and given intensive training.

Tennessee's example shows that, with strong leadership, the physical restraint of patients can be minimized -- indeed, nearly eliminated -- safely and without exorbitant cost.

"If we could do it here," said Frances Washburn, deputy superintendent of Clover Bottom Development Center, which includes the Jordan unit, "it can be done anywhere."

But the routine and frequently dangerous use of restraints persists elsewhere, even though the solutions are often simple and straightforward: better training, stronger oversight, uniform standards and the collection and sharing of information.

Federal officials and health groups say they are working on it.

The U.S. Center for Mental Health Services has begun a five-state pilot program to collect restraint and seclusion data. The U.S. Department of Veterans Affairs is tracking deaths more closely.

The Joint Commission, the nation's leading hospital accreditation organization, has strengthened its guidelines on restraint and seclusion. And the American Medical Association has begun studying the use of restraints on children.

"Those steps sound pretty inadequate to me," said Dr. Joseph Woolston, medical director for children's psychiatric services at Yale-New Haven Hospital. "This sort of half-hearted patchwork approach will probably do more harm than good by giving an illusion that something is happening when it is not."

So for now, it is left to individual hospitals to find their own way. Those committed to the task illustrate what can be done.

Riverview Hospital for Children and Youth, a state-run psychiatric hospital in Middletown, Conn., uses an intensive training program that emphasizes non-physical intervention when a patient loses control.

"These situations are often chaotic and unpredictable, and without proper training, staffers are just winging it," says Linda Steiger, executive director of Wisconsin-based Crisis Prevention Institute.

CPI, a leading private training company, provides instruction to Riverview workers. The cost is minimal: $895 per person for a four-day program to teach a small number of designated staffers, who then instruct their peers.

Tighter procedures also emphasize that every restraint is a major step -- literally, a matter of life and death.

At Riverview, a staffer is required to constantly monitor anyone in mechanical restraints. That ensures a patient's vital signs remain strong, and provides an incentive to end the intervention as soon as the patient regains control.

At Tennessee's Jordan Center, patient treatment plans that include the use of restraint are, for the most part, rejected. And every use of emergency restraint is investigated and must be defended.

"When forced to go through the self-analysis and justifications, they solve it at a lower level the next time and without restraints," said Thomas J. Sullivan, who heads Tennessee's Division of Mental Retardation Services. "Of course, this requires staff to give up total control."

Emergency restraints are so infrequent now that Sullivan gets an e-mail message every time they are used. He's gotten an average of just two to three e-mails per month since January.

Accountability means staffers share more information and learn from the mistakes of others. Techniques found to be dangerous, such as face-down floor holds and mouth coverings, have been outlawed in certain places as a result.

But tough lessons learned by individual hospitals typically aren't shared with facilities on the other side of town or 10 states away. Each hospital is left to reinvent procedures or learn the hard way -- through the death of a patient.

It doesn't have to be that way.

New York state has reduced restraint use and the number of related deaths by requiring the reporting of usage rates and by investigating all deaths.

After New York required all mental health facilities to say how often they use restraints -- and published the numbers -- the top three users revamped their policies and brought their numbers down.

When it came to deaths, the state used to allow each hospital to decide which ones were questionable enough to report. It was notified of 150 cases over three years. Once mandatory reporting

of every death was instituted 20 years ago, the number of deaths requiring further investigation rose to 400 a year.

"When people have a choice in classifying deaths -- with one choice resulting in tremendous scrutiny, the other resulting in none, what do you think they're going to do?" said Clarence Sundram, the former chairman of the independent New York agency that tracks and investigates deaths.

Accountability has produced results. Restraint-related deaths in the past five years have been cut nearly in half as compared with the preceding five years, New York state records show.

Nationwide accountability could accomplish the same.

"There needs to be some kind of state-by-state evaluation to gather comparative statistics and give an annual report to Congress," said Dr. E. Fuller Torrey, a prominent psychiatrist and author.

"Until you embarrass the individual states," Torrey said, "nothing will be done."

The federal government has shown a willingness to intercede on this very issue -- in response to charges that the elderly were being abused.

When the U.S. Food and Drug Administration estimated in 1992 that more than 100 people annually were killed through the use of mechanical restraints in nursing homes, the agency tightened rules on their use.

"We also thought these cases were flukes," said the FDA's Carol Herman, "until we started digging."

The FDA now considers lap and wheelchair belts, fabric body holders and restraint vests to be prescription devices. Manufacturers are subject to FDA inspections to ensure quality control.

Such steps, advocates say, have both reduced and improved the use of restraints. In the mental health field, strong and independent government oversight can weed out bad practices and bad facilities as well, they say.

"We can't do it alone," said Curtis L. Decker of the National Association of Protection and Advocacy Systems. "The only way to truly protect patients is through a large, comprehensive monitoring program."

That means a system where government regulators, not the industry, are charged with oversight, he said. An internal patient grievance system would be bolstered by a well-funded network of independent advocates trained in death investigations.

More than money, though, many analysts say a culture in which restraints are used too soon, too frequently and for the wrong reasons must be changed.

"The single biggest prevention method is the avoidance of restraints to begin with," Sundram said. "It is often the training and opinions of staff that dictate restraints, rather than patient behavior."

In Tennessee, "the changes were top-down, bottom-up and a hard sell everywhere," Sullivan said. Before taking the top Tennessee job, Sullivan spent 27 years as an official in Connecticut's Department of Mental Retardation.

Reducing restraint use was just one of many changes forced on Tennessee by two lawsuits filed by the U.S. Department of Justice and by patient advocates. "It was a system that was disintegrating," said Ruthie Beckwith of People First of Tennessee, a patient advocacy organization that sued the state.

The state responded with new leadership, more money and staff and an intensive training regimen emphasizing calming words instead of brute force.

The total cost for the Jordan Center: $12,665 for training in restraint use and alternative methods; $255,372 annually in additional staffing to address not only restraint issues but massive deficiencies in overall patient care.

The changes in technique weren't easy on staff. About a half-dozen aides quit. Others groused. But most stayed and changed.

"It was a rough couple of months," said Robert Zavala, an aide at Jordan. "At first, they just told us we couldn't put our hands on them. Everyone was like, 'Oh, so all I can do now is run away?' "

Bernard Simons, the Clover Bottom superintendent who oversaw the transition, remembers a defining moment. He received a frantic call from staffers at Jordan saying a patient was smashing furniture and asking whether they could restrain him.

"I said, 'Let him break it,' " Simons said. "So you're going to risk hurting yourself or the patient for a $100 coffee table? The state will buy a new one."

The changes are both profound and surprising to staff and patients who remember the old ways.

"Before, we weren't earning their respect, it was just fear," said Overton, the burly aide who still wears a belt that says "Boss."

"Now, I'm more of a counselor or big brother than an enforcer," Overton said. Like a Cold War relic, he now uses skills other than just his brawn, such as his woodworking knowledge, which he passes on to patients in a new class he teaches.

"I used to get shuffled a whole lot of times when I would go off and hit someone," said David Holland, 24, who has been at the Jordan Center for 2 1/2 years. "Now, they give us a lot more time to chill out, calm down. It's getting better each day."

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Prepared Statement of Michael Hash

Chairman Roth, Senator Moynihan, distinguished committee members, thank you for inviting me to discuss the importance of preventing inappropriate use of seclusion and restraints in psychiatric treatment facilities. We applaud the efforts of Senators Lieberman and Dodd and Congresswoman DeGette to address this issue. We also recognize the importance of the work done by journalists at the Hartford Courant on this issue. And we greatly appreciate the insights and advice provided to us on this by our colleagues at the General Accounting Office.

We are profoundly disturbed by the reports of deaths and injuries resulting from the inappropriate use of seclusion and restraints in mental health facilities. We strongly agree with patient advocates that use of seclusion and restraints must be recorded, reported, and always a last resort. We are taking steps to ensure that use of restraints or seclusion to manage behavior is an emergency measure reserved for unanticipated, severely aggressive or destructive behavior that places the patient or others in imminent danger. We have removed certification from facilities where egregious violations have been documented. And we have a comprehensive review underway of facilities owned by the Charter Corp. because of the extent of problems identified in this chain.

In July, we mandated that all hospitals providing services to Medicare and Medicaid beneficiaries recognize specific patient rights, including the right to be free

from inappropriate use of seclusion and restraints. Under these important new rules:

- seclusion and restraints may not be used in any form as a means of coercion, discipline, convenience, or retaliation;
- hospitals must report to us any death that occurs while a patient is restrained or in seclusion, and we in turn will report it to the state Protection and Advocacy Agencies;
- a physician or state-approved licensed independent practitioner must conduct a face-to-face evaluation for any patient placed in seclusion or restraints for behavioral management within one hour of initiation;
- hospital staff must have training in the appropriate and safe use of seclusion and restraints; and
- hospitals must provide a patient or family members with a formal notice of the right to be free from inappropriate seclusion and restraints and other rights at the time of admission.

In addition to the reporting of deaths, we are considering regulations defining "serious injuries" related to seclusion and restraints for which reporting should be mandatory. We are working with other federal and state agencies to determine the best system for maintaining comprehensive records of seclusion and restraints incidents. And we are working to extend strong protections to individuals in residential treatment facilities, congregate care centers, and community-based settings.

We are confident that our regulations will be effective in reducing inappropriate use of seclusion and restraints in inpatient hospitals. We have had solid success we have had for patients in nursing homes with regulations published in 1990, and for patients in intermediate care facilities for the mentally retarded with regulations published in 1988. We also are encouraged by the success of states, such as Pennsylvania and New York, in dramatically reducing use of seclusion and restraints in mental health facilities.

Also, importantly, we are working with the Joint Commission on Accreditation of Healthcare Organizations to improve its performance in monitoring use of seclusion and restraints. Under law, the Joint Commission, rather than federal or state surveyors, monitors the quality of care and certifies compliance with federal regulations in most hospitals, including psychiatric hospitals. In August, we met one of our key goals for improving Joint Commission performance when it announced that hospitals will no longer be given notices of random surveys.

BACKGROUND

Medicare and Medicaid play a key role in serving and protecting individuals with psychiatric disorders. Regulations for institutional health care providers serving individuals enrolled in these programs, known as "conditions of participation," apply to all patients they treat, not just those covered by Medicare or Medicaid.

We first proposed protections from inappropriate use of seclusion and restraints in psychiatric and other hospitals in a 1997 Notice of Proposed Rule Making that included a number of important patient protections in our conditions of participation for hospitals.

Because of the urgent need to enact protections against inappropriate use of seclusion and restraints, we "carved out" the patient's rights section of this proposed regulation that includes seclusion and restraint requirements and issued it as an interim final regulation in July of this year. It became effective August 2, 1999. Other patient rights in this regulation include the right to privacy and confidentiality, to file grievances, to have advance directives followed, to participate in developing and implementing care plans, and to be free from verbal and physical abuse.

Under this rule, restraints can, of course, be used in the normal course of medical or surgical care, for example to protect intravenous tubing or when a patient is undergoing surgery. Use for managing behavioral management is allowed only when all less restrictive measures have failed and unanticipated severely aggressive or destructive behavior places the patient or others in imminent danger of harm.

If patients are placed in seclusion or restraints because they have become violent or aggressive, they must be seen and evaluated by a physician (or other qualified licensed independent practitioner as determined by each state) within one hour. This one-hour rule is designed to ensure that the seclusion or restraints are warranted and properly applied, and it must be met regardless of how briefly seclusion or restraints are used.

The new protections apply to all acute care, psychiatric, rehabilitation, long-term, children's, and substance abuse treatment hospitals. The rule is what is known as an "interim final" rule, for which public comments were accepted through September 2. We specifically solicited comments on key outstanding issues. For exam-

ple, we asked for input on how to define "serious injuries" related to seclusion or restraints that should be reported, and on the utility of such reports. We hope to address these outstanding issues in a final rule.

To further assist providers and the public in understanding this regulation, we are developing a list of frequently asked questions about it to post on our medicare.gov website. We also are developing further interpretive guidance for providers on how to comply with the regulation.

Recording and Reporting

It is essential that all facilities maintain records in a standard way and report when deaths are associated with seclusion and restraints for incorporation into a comprehensive database. State experience makes it abundantly clear that reporting systems are highly effective. New York, for example, requires that all deaths of mental health consumers be reported to the state's Protection and Advocacy agency, which is authorized to investigate. Recommendations based on these investigations have significantly reduced use of seclusion and restraints and brought about other substantial improvements in care.

We solicited public comments on how the optimal database would function in the Patient Rights regulation we published in July. We will work with federal and state colleagues to determine whether any existing databases can help meet this need. The Food and Drug Administration receives data on deaths and other problems related to restraints that are considered medical devices. The Substance Abuse and Mental Health Services Administration and state Protection and Advocacy agencies also monitor data on seclusion and restraint-related problems. The HHS Inspector General is conducting studies on existing patient abuse reporting systems and oversight of psychiatric hospitals. And we are working with states and survey agencies to develop a standardized form for reporting deaths to ensure consistency and comparability of data from across the nation. For the time being, individuals concerned about the quality of care provided at any specific facility can contact state survey agencies or Health Care Financing Administration Regional Offices. These offices are able to verify whether a specific facility has been cited for violation of these or other patient safety protections.

Staff Training

Training for staff on use of seclusion and restraints is essential to minimizing any inappropriate use. Our July Patient's Rights regulation specifically mandates that "all staff who have direct patient contact must have ongoing education and training in proper and safe use of seclusion and restraint application and techniques." They must also have ongoing training on "alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraint or seclusion."

Restraint in Other Facilities

We first published regulations addressing use of restraints in1988 for intermediate care facilities for the mentally retarded. These regulations require that restraints be used only when the danger of the behavior outweighs the danger of the use of restraints as an intervention. And they may only be used as an integral part of an individual program plan intended to lead to less restrictive means of managing the behavior causing the use of restraints.

These facilities must maintain documentation for each use of seclusion and restraints, and we intend to reevaluate these rules as part of an overall assessment of reporting requirements. Extensive training requirements for staff in intermediate care facilities for the mentally retarded specifically include education on proper use of, and alternatives to, seclusion and restraints.

We published regulations addressing the use of restraints in nursing homes in 1990. Nursing home residents were given the right to be free from seclusion and physical restraints, as well as "chemical" restraints with psychoactive drugs, for any reason other than the treatment of a medical condition.

In a 1998 Report to Congress, we found that these regulations have helped to dramatically cut the inappropriate use of physical restraint and psychoactive drugs. Also in 1998, we launched a broad initiative to increase the quality and level of both state and federal oversight of nursing home care, which also is helping to increase protections against inappropriate use of seclusion and restraints. This initiative features enhanced survey procedures and guidelines for preventing abuse and neglect in nursing homes, including review of training for nursing home staff.

We collect data on use of restraints in nursing homes through the "minimum data set," which must be completed and periodically updated for each patient, as well as through routine annual surveys. This allows us to track the number and types of patients for whom restraints are used at each facility.

We are considering crosscutting seclusion and restraint standards that would affect all providers that receive Medicare and Medicaid funding. And we are currently developing regulations to ensure that protections against inappropriate use of seclusion and restraints are in place for other specific settings where vulnerable psychiatric patients receive care.

For example, individuals receiving services under Medicaid provisions for covering psychiatric services to those under age 21 are not currently covered by existing regulations when receiving care in residential treatment centers. We have solicited comments from patient advocacy organizations, as well as state administrators and provider groups, on how this regulation should be constructed. We expect to publish a regulation affording such protection next Spring. As with our other regulations governing participation in Medicare and Medicaid, the rules would apply to all patients served by these facilities.

We also are working together with states to explore both regulatory and non-regulatory protections for the increasing number of individuals with psychiatric disorders who are receiving services under "home and community based services" Medicaid waivers. These individuals can receive services in their private residences, group homes, day treatment facilities, and a variety of other non-institutional settings. We are seeking more information on the extent to which seclusion and restraints are used in such settings. We are working with states to develop guidance for monitoring care in these settings. We are looking for innovative quality assurance practices among the states in these community-based care settings. We want to ensure that patient advocacy groups have a strong voice in these efforts as we proceed.

Accreditation

Accreditation of facilities providing psychiatric care, which includes certification of compliance with all Medicare and Medicaid regulations, is primarily carried out by private bodies. The Joint Commission on Accreditation of Healthcare Organizations accredits most psychiatric hospitals. Other accrediting bodies for psychiatric care providers include the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, and the American Osteopathic Association.

We have initiated an accreditation action plan to improve the quality of oversight by the Joint Commission, which should help to further increase protection from inappropriate seclusion and restraints. In this action plan, we will:

- articulate clear criteria for Joint Commission performance;
- review and strengthen federal oversight of Joint Commission surveys;
- conduct federal investigations of complaints about substandard care in facilities that the Joint Commission has said are in compliance with federal standards;
- work with the Joint Commission as it develops its annual survey priorities to encourage a focus on critical issues such as medication errors;
- encourage more rigorous review of hospitals' internal quality improvement efforts;
- encourage more random selection of records for review;
- urge the Joint Commission to conduct more unannounced surveys; and
- evaluate removal of restrictions on releasing Joint Commission survey data to the public.

As mentioned above, we met one of these key goals when the Joint Commission in August announced that it will no longer give hospitals notices of random surveys and instead will conduct these surveys unannounced. We expect that, as we have seen in our nursing home enforcement initiative, unannounced surveys will provide better insight into the true quality of care being provided and any problems that need to be addressed.

CONCLUSION

Our new regulations are a major step in directly addressing the inappropriate use of seclusion and restraints in mental health facilities. We intend to enforce them vigorously and to aggressively address situations in which patients are endangered. We are committed to developing further regulations and exploring other avenues for protecting vulnerable psychiatric patients and ensuring that they are treated with dignity and the highest professional standards. And we look forward to continued collaboration in these efforts with patient advocates, provider groups, and our federal and state colleagues. I thank you for holding this hearing, and I am happy to answer your questions.

PREPARED STATEMENT OF TERRANCE JOHNSON

Greetings,

My name is Terrance Johnson. I am a licensed social worker with a Masters degree in Social Work from the University of Pennsylvania. Thank you for the opportunity to speak with you on the topic of seclusion and restraints.

Recently I worked with the staff of CBS's 60 Minutes documenting the dangers that exist in the children's ward of a psychiatric hospital. But I believe that what I experienced while working under cover as a Mental Health Worker may go far beyond that particular hospital and reflects the numerous deficiencies of a nation-wide industry that often fails to provide quality mental health care.

At its core this was a story about children in need.

I have seen these children in need enter and leave our hospitals without receiving help. I saw children spending weeks in a facility receiving little assistance to help them overcome, cope with, or even discover the issues that brought them to the hospital.

I saw how children who entered the facility spent the majority of their time with untrained Mental Health Workers who lacked both the skills and knowledge necessary to direct these children's recovery. These Mental Health Workers were well-intentioned people who were trying to make a living on the $8.32 that this hospital paid them. They seemed to be trying to survive their daily shifts with as few incidents as possible. Unfortunately, these Mental Health Workers often found themselves in the midst of situations that they had not been trained to handle.

Typically the untrained worker's only recourse is an authoritative paradigm consisting of an arsenal of commands such as "shut-up," "sit-down," and "calm-down." Untrained, they order the children to be and act "normal," warning that their failure to do so may result in seclusion or restraint. At times these untrained workers run these psychiatric units with little or no supervision and with the unchecked authority to determine who gets seclusion and who get restrained.

These untrained workers interact with children who are often living lives that many people in his room could not imagine. Some lived in foster care. Some were abused. Many were teased relentlessly in schools. These stressed, depressed, and suicidal children are locked in hospitals with untrained workers who demand strict compliance at all times. Often children and workers confront each other over rules and orders as mundane as standing in a straight line. If the child refuses, a battle often ensues that may escalate to the point where the worker sends the child to seclusion or restrains her.

I recall several situations similar to this. I recall these children confronting nearly surreal life situations not having anyone to help them. I remember a specific child who would act-out so that the workers would give him individual attention. He only received individual help when he started hitting the walls or when he refused to take his psychotropic medicines. I can still hear the words of the nurse, "you have 5 minutes—you either take this injection or you're going to be tied down." I recall trying to talk to this child and being reprimanded by the managing nurse—who told me that we did not have the time or staff to spend this much energy on one child.

If a restraint is not performed properly a child can be hurt or even killed in it. I observed restraints where none of the people performing the restraint had received any training on when the procedure was necessary or how it was to be carried out. I observed situations where workers unknowingly handled the children in ways that led to injury for the workers and the children. A number of the restraints that I observed could have been avoided had the workers involved been properly trained.

In my experience as a social worker I have seen the opposite of this environment. I have witnessed restraint-free environments where children grow and overcome the challenges that brought them to the hospital. In these environments all of the direct care workers are trained and have replaced the authoritative approach with educated compassion and empathy.

With the proper training many seclusion and restraints can be avoided. But this will require raising health care standards across the board. This will require that every direct care worker receive the necessary training to carry out his or her job duties.

I believe that we can reduce the frequency of seclusions and restraints and improve the quality of care in mental hospitals by making a few simple changes:

1) Provide clearer guidelines that require that all staff be trained in the proper use of restraints.

2) Train all direct care workers in how to work with the population for which they are responsible.

3) Require that any facility receiving federal funding be independently monitored to ensure compliance with national health care standards.

Prepared Statement of Dennis Klima

Mr. Chairman, I am Dennis Klima, President/CEO of Bayhealth Medical Center with hospitals in Dover and Milford, Delaware. Bayhealth is a full-service provider of health care to a diverse community, offering everything from inpatient rehabilitation care to outpatient and long-term care. We also offer comprehensive behavioral and psychiatric services at the outpatient, inpatient, and residential treatment levels. I appreciate this opportunity to present my perspective on the use of restraint and seclusion and patient safety at our St. Jones Center for Behavioral Health.

Recent reports of patient deaths and injuries from the use of restraint and seclusion have drawn attention to the risks of such interventions for patients. I appear before you today, a representative of hospitals and health systems, to say we are all saddened when tragedy occurs, and that the hospital field is committed to finding solutions that will prevent any future deaths and injuries resulting from restraint and seclusion. Even one death or serious injury, is "one too many."

At Bayhealth we are reviewing our policies to ensure we are doing all we can to prevent improper use of restraint or seclusion. In addition, to help all hospitals and health systems prevent death and injury related to the use of restraints or seclusion, the American Hospital Association and the National Association of Psychiatric Health Systems issued "Guiding Principles on Restraint and Seclusion for Behavioral Health Services" to their members earlier this year.

PATIENT SAFETY

Our number one priority at Bayhealth's St. Jones Center is the health and safety of the individuals who come to us for treatment of psychiatric and addictive disorders. These patients come to us at one of the most difficult and vulnerable times of their lives. Individuals may be suicidal, have difficulty handling their anger, suffer from mental illness, or suffer from drug use that affects their behavior. They come to Bayhealth because their problems are so serious that they can not be treated in other settings, and they are most often admitted because they are a danger to themselves or others.

Patients' threat to themselves is real. Over the last 15 years the emphasis in mental health care has shifted from the inpatient setting to alternative treatment settings. This has meant that patient acuity in the inpatient setting is now much higher. Patients are more seriously ill than in the past and more likely to be in the hospital because they have attempted suicide or attacked others. When necessary, the act of restraining these patients prevents them from harming themselves or others.

Out of control patients also threatens the safety of health care workers. The National Institute for Occupational Safety and Health (NIOSH) has found that most nonfatal workplace assaults occur in service settings such as hospitals, nursing homes, and social services agencies. Health care patients commit 48 percent of nonfatal assaults in the workplace.

According to the Department of Justice, mental health professionals ranked sixth on a list of occupations with the greatest risk of attacks—behind police officers, private security guards, prison guards, taxi drivers and bartenders.

When used properly, restraint and seclusion can be life saving and injury-sparing emergency interventions for patient and healthcare workers. However, restraint and seclusion should only be used when less restrictive methods are considered and are deemed not feasible.

PROPER USE OF RESTRAINT AND SECLUSION

Restraint and seclusion are emergency safety interventions initiated to protect the safety of a patient or others. These interventions are implemented and monitored according to detailed hospital policies and are documented in medical records. Our policies and procedures regarding restraint and seclusion are clinically sound and clear, understood, and implemented appropriately by all staff.

At Bayhealth, restraint and seclusion are only employed to ensure safety. They are never used as a punishment. The philosophy of the policy and the training is focused on minimizing or avoiding the use of seclusion and restraint whenever possible. Every effort is made to maintain the patient's dignity and the humanity of the staff in the process. The nursing staff is trained to evaluate the patient in distress and respond with an individualized intervention. Efforts are made to assist patients in verbalizing rather than acting on their emotions.

All psychiatric staff and many other hospital staff are trained in how to work as a psychiatric emergency assistance team (PEAT). Yearly refresher courses and evaluations are conducted to ensure competency.

The focus of the training is to manage the potentially violent patient in a safe and dignified manner. The techniques of restraining a violent patient are in the context of de-escalation. The various causes of violent behavior are reviewed, so that the staff may be able to understand the individual in question. A variety of staff responses are also reviewed with a special focus on those responses, which may aggravate versus alleviate the situation. The staff is taught verbal and non-verbal interventions to employ. The overarching principle is to try to engage the patient and offer choices. In this way the patient can maintain a sense of control without resorting to violence. Should the patient require physical restraint, the staff is taught to work as a team. Specific physical techniques are employed that minimize danger to staff and patients.

OVERSIGHT OF RESTRAINT AND SECLUSION

There are—and should be—strong oversight mechanisms in place at the federal, state and facility levels. A wide variety of federal, state and local agencies are already empowered to inspect and sanction hospitals when a death or major injury occurs. These include the Joint Commission on Accreditation of Healthcare Organizations, the Health Care Financing Administration, and state licensing boards.

In the last few years, the Joint Commission has made proper use of restraint and seclusion a priority and strengthened their requirements. Every facility is required to carefully review any unexpected death or serious injury and must take swift action to correct any identified problems. Failure to do so could lead to loss of accreditation and therefore Medicare and Medicaid funding.

I appreciate Congress' desire to lend its weight in eliminating death and serious injury resulting from restraint and seclusion, but I believe legislation that overlaps existing regulatory requirements may be unwarranted. HCFA and the Joint Commission are already having difficulty in reconciling their different approaches.

HCFA recently increased its oversight by issuing new restraint and seclusion standards as part of a set of conditions hospitals must comply with to participate in Medicare. They developed two sets of standards one that applies to medical and surgical patients and another for patients who are restrained or secluded for behavior management in any setting. The agency's new standards include restrictions on who can order restraint use and how restraints can be ordered; requires use of restraint and seclusion to be continually assessed, monitored and reevaluated; stipulates ongoing training of direct care staff in the proper and safe use of restraints; and requires hospitals to report to HCFA on their use of restraints.

I believe HCFA's use of the process of amending the conditions of participation is the appropriate means to address oversight of the use of restraint and seclusion. The conditions of participation also have the advantage of being updated, something not easily accomplished through legislation.

Many of HCFA's standards in the conditions of participation reflect the "best practices" currently used. The standards also address the critical training issues raised in a "60 Minutes" piece and the need for reporting called for in the Government Accounting Office's October report. However, I, along with many other hospital administrators, am extremely concerned about HCFA's provision that requires a face-to-face physician evaluation of a patient within one hour of the initiation of restraint and seclusion. This particular regulation is troubling for three reasons.

First, it seeks to replace a physician's medical judgement with a regulatory requirement. While it is sensible to require a timely and clinically appropriate evaluation, it is not feasible or clinically necessary to require a face-to-face physician evaluation in every case. A physician assessment should always be done, but the physician should be the one to determine whether a face-to-face evaluation is necessary within one hour.

The intent and the goal of the standard would be met by requiring the physician to evaluate the need for the order over the phone through discussions with the nurse or other caregiver who initiated the intervention within one hour. If a physician comes to the hospital to conduct the evaluation, he or she would most likely be asking that same person about the circumstances that led to the intervention and whether, given their knowledge of the patient, they believe it necessary to continue the intervention. The physician should be the one to determine whether a face-to-face evaluation within one hour is necessary. We should not get in the habit of regulating medical practice or requiring physicians to be substituted for nurses when a professional nurses' actions and judgements are appropriate.

HCFA's requirement disregards a nurse's role in assessing patients. At Bayhealth we trust our nurses to do their job well. It is appropriate for the physicians to order restraints or seclusion and because of the quick time frame, this is often accomplished over the phone. But the doctors depend, and rightly so, on the assessment of the professionally trained caregiver on the scene the nurse.

Second, implementing this provision will be expensive and difficult. Difficult because physicians may be asked to leave less stable patients to comply with this regulation. Alternatively, compliance may require employing additional physicians, further adding to the cost of care.

Third, the regulation causes me grave concern because HCFA failed to consult with the hospital field in the development of this particular provision. Usually a detailed provision, such as the one-hour face-to-face rule, first appears in HCFA's proposed regulation, and the field is given 60 days to provide comments. Therefore, HCFA issues a final rule, duly considering submitted comments. This provision was not included in a proposed rule and therefore, no consideration was given to comments from those most affected before they became effective.

The agency also failed to conduct a meaningful impact analysis. Unable to quantify either the costs or benefits associated with the standard it has adopted, HCFA simply suggests that the final rule should impose no significant additional burden on the 80 percent of hospitals accredited by the Joint Commission.

However, the commission standards do not require hospitals to have a physician available for a face-to-face evaluation within one hour of the use of restraint and seclusion. Finally, HCFA's 30-day notice prior to the rule's effective date completely ignored the lead time it takes for hospitals to change their operational policies and procedures, particularly those that must be approved by and carried out by the medical staff, who are generally not hospital employees.

CONCLUSION

There should be zero tolerance for deaths and injury from the use of restraint or seclusion. Hospitals and health systems are committed to working with consumers, families, regulatory and accrediting agencies, Congress, and others to ensure that the systems designed to protect patients are working, and that clear and appropriate guidelines and standards are in place to protect patients and maintain their dignity.

HCFA has the authority to establish appropriate standards to address and investigate any inappropriate use of restraint and seclusion. Legislation establishing separate standards and reporting requirements would be duplicative and unnecessary. Mr. Chairman, I appreciate Senators Lieberman and Dodd and all senators and representatives who have turned their attention to this critical issue. Thank you again for the opportunity to present my views.

PREPARED STATEMENT OF HON. JOE LIEBERMAN

Mr. Chairman, Ranking Member, I would like to start today by extending my sympathy to the wife and family of Senator John Chafee. I worked closely with John on environmental, health, and budget issues, and was the better for the time we spent together. He was a man who got things done, a man who was uncommonly good at finding common ground, and at doing what was in the best interest of the nation, whether in pursuit of a higher quality of healthcare for all Americans, a better stewardship of our natural resources, or a stronger safety net for the most vulnerable among us.

Mr. Chairman, I applaud your decision to hold a hearing on the use of restraints. The reports of deaths roll back a door on a medieval world where facilities and providers are not being held accountable for some of their more barbaric practices.

This year, over 240,000 individuals will be institutionalized for mental health care—as many people as live in Rochester or Norfolk or Las Vegas, or Anchorage. Tragically, the GAO notes, "the safeguards currently in place are not comprehensive and fail to fully ensure the rights and safety of these individuals."

The GAO has identified at least twenty-four mental health patients that died last year under restraints and seclusion in mental health institutions. This number, the GAO readily concedes, is a vast underestimate because there are few reporting requirements, although the GAO findings far outstrip the number of deaths uncovered by a searing set of articles in the Hartford Courant last year. The Courant discovered that over 142 patients died over the last decade in mental health institutions due to the use of restraints and seclusion.

I believe that many, if not most, of these deaths were needless, and I believe they can be stopped if we hold staff and facilities accountable for their use of restraints

and seclusion. We have no intention of prohibiting the medical community's use of restraint. But if restraints are going to be used—and people are going to get injured, or worse—families and the community should have the right to know the circumstances of the injuries, and the identity of the facility where deaths have occurred.

The legislation I have introduced with Senator Dodd and other members of the Connecticut delegation is based on this commitment to accountability.

Under our legislation, no patient will be placed in restraints by a nameless health care provider in the middle of the night, behind a wall of secrecy. If restraints are to be used, a physician or licensed independent practitioner will have to sign the order, and that person will be held accountable for deaths that occur under his or her authority. Under our legislation, the public will have an absolute right to reports of deaths from restraints and seclusion. No facility will be able to conceal a record of deaths or injuries from the families of the mentally-ill, or parents and individuals seeking care for their love ones.

Our legislation enjoys the support of accrediting organizations, psychiatrists, facilities, patients, and their families. With your permission, I would like to enter their letters of support into the record.

Since the Hartford Courant articles were published, I am delighted to report, many organizations have taken responsibility for preventing additional deaths. "60 Minutes," and "Fox Files" both carried investigative pieces on abusive restraints. The Administration, through the Health Care Finance Administration, has issued regulations on the use of restraints in over 6,000 hospitals. Two Committees of Congress—the Labor/HHS Subcommittee of Appropriations and the Committee on Health, Education, Labor and Pensions—have addressed the use of restraints through legislation.

I urge the Finance Committee to join this broad effort and hold mental health providers accountable for their use of restraints and prevent the deaths from continuing.

NEWS RELEASE

U.S. SENATOR JOE LIEBERMAN
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Home Page: http://www.senate.gov/~lieberman/

FOR IMMEDIATE RELEASE
Special Attention ***Medicaid/Medicare/Restraints*** October 25, 1999

LIEBERMAN CALLS FOR ACCOUNTABILITY FROM MENTAL HEALTH PROVIDERS WHEN RESTRAINTS RESULT IN INJURIES OR DEATH

WASHINGTON - Senator Joseph Lieberman, D-Conn., Tuesday urged passage of legislation regulating the use of restraints in mental health institutions as a way of holding health-care providers accountable for the decisions they make outside of public view.

In a hearing before the Senate Finance Committee, Lieberman said the families of mental health patients have an absolute right to information about restraints used on their loved ones, as well as the history of restraint use at institutions they may be considering for loved ones.

Lieberman and Sen. Chris Dodd, D-Conn., along with Rep. Rosa DeLauro, D-Conn., and others, have introduced legislation that would extend existing nursing home standards on the use of restraints to mental health facilities receiving public funds in the form of Medicare and Medicaid payments. The bill requires authorization from a "physician or licensed independent practitioner" before restraints are used, and calls for systematic reporting of deaths and serious injuries caused by restraints.

"The reports of deaths roll back a door on a medieval world where facilities and providers are not being held accountable for some of their more barbaric practices," Lieberman said. "Under our legislation, no patient will be placed in restraints by some nameless health care provider in the middle of the night. We have no intention of prohibiting the medical community's use of restraint. But if they are to be used - and people are going to get injured, or worse - families and the community should have the right to know the circumstances of the injuries, or deaths, and where they occurred."

Earlier this month, the General Accounting Office issued a report that identified 24 deaths involving the use of restraints in fiscal year 1998 in mental health facilities receiving Medicaid and Medicare. The GAO readily conceded its figures were an underestimate because there is no systematic reporting of these incidents. GAO recommendations tracked the Lieberman-Dodd legislation, calling for expanded protections for the mentally ill, including reporting and staff training requirements.

The issue of deadly restraints was exposed last year by the *Hartford Courant* in an October series that detailed 142 deaths from restraint and seclusion in mental health facilities in 30 states over the last decade. More then 26 percent of the fatalities were to children under the age of 17. That's nearly twice the proportion of children in mental health institutions.

S. 736 -- THE FREEDOM FROM RESTRAINT ACT OF 1999 (as amended)

The Freedom from Restraint Act extends current restraint protections for nursing home residents to all mental health patients in facilities receiving Medicaid and Medicare funds, and requires that deaths and serious injuries to mental health patients be reported. The legislation builds on successful laws that have reduced the use of restraints in nursing homes by one-third since 1991 and which patients, physicians, and providers have found workable. The protections can be implemented quickly and broadly due to their foundation in existing laws and policies, but hold mental health facilities accountable for their use of restraints.

Right To Be Free From Restraints

Mental health patients will be protected by restrictions on the use of restraints. Under the bill, providers shall "protect and promote the right of each such patient to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience".

The bill does not prohibit the use of restraints, but establishes procedural safeguards to protect patients from their overuse. Under the legislation, a restraint may only be imposed "to ensure the physical safety of the individual or other individuals in the care or custody of the provider, a staff member, or others" with a written order from a physician or licensed independent practitioner (permitted by the State and the facility to issue restraint orders) specifying the "duration and circumstances" under which the restraints are to be used. Under emergency circumstances, specified by the Secretary of Health and Human Services, restraints may be used until a written order can be obtained.

Rather than create a entirely new standard. the bill simply broadens legislation that has successfully protected nursing home residents (passed in 1987 as part of the Omnibus Budget Reconciliation Act) to include the mental health population. In nursing homes, the restraint standard has proven workable and is credited for the dramatic reduction in the use of restraints by nursing homes of over one-third in the last eight years alone, according to the Health Care Finance Administration.

Required Reporting of Deaths and Sentinel Injuries

When a patient dies or is seriously injured as a result of restraint and seclusion, the facility should have to tell the authorities. Families choosing a facilities to provide care to a child should have access to reports of deaths or substantial numbers of serious injuries. The reporting requirements are only triggered when a death or serious unexpected injury occurs. Facilities that are death and sentinel event free will not need to file any reports.

Serious, unexpected injuries to a mental health patient that fall short of death will be reported to HHS or to the facility's national accrediting body in the case of an accredited facility. Upon receipt of a report, either HHS or the national accrediting body will ensure that the provider investigates the injury, determines its cause, and takes action to correct the problem and reduce the likelihood of its repetition. This requirement builds upon existing "sentinel event" reporting practices and definitions of the Joint Committee on Accreditation of Healthcare Organizations.

The reports of unexpected serious injuries, deaths, and the steps to prevent their reoccurrence will be added to the publicly available database. If the report involves a death, or a pattern of poor performance emerges for a facility, that facility's name and address will be included in the publicly available database.

Death of a mental health patient triggers additional reporting. Upon a "sentinel event" death, the facility is required to file a report with the police, the state licensing agency, the protection and advocacy system, any relevant national accrediting body and the Department of Health and Human Services.

Organizations Supporting
S. 736 The Freedom from Restraint Act of 1999

American Health Care Association
American Association of Community Psychiatrists
American Psychiatric Nurses Association
Bazelon Center for Mental Health Law
Community Addiction Services of Indiana, Inc.
Connecticut Children's Medical Center
Federation of Families for Children's Mental Health
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
National Alliance for the Mentally Ill
National Mental Health Association
National Association of Protection and Advocacy Systems (NAPAS)
National Council for Community Behavioral Healthcare

National Mental Health Association

1021 Prince Street, Alexandria, VA 22314-2971 • Phone (703) 684-7722 • Fax (703) 684-5968 • TTY (800) 433-5959 • www.nmha.org

Monty Moeller, Chair of the Board • Michael M. Faenza, President and CEO

October 22, 1999

The Honorable Joseph Lieberman
SH-706 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Lieberman:

On behalf of the National Mental Health Association (NMHA), I am writing to reaffirm our support for the "Freedom From Restraint Act" (S. 736). While the recent interim seclusion and restraints regulations issued by the Health Care Financing Administration (HCFA) represent a significant step forward, there is no question that Congress must enact S. 736 as soon as possible in order to save lives.

I was shocked by the findings of a September 1999 General Accounting Office (GAO) report which confirmed -- that in 1998 alone -- 24 children and adults died in psychiatric facilities because of the abusive use of restraints. "Because reporting is so fragmentary, we believe that **many more deaths** related to restraint or seclusion may have occurred." If projected over a 10 period, the GAO study appears to show that 250 deaths occurred in the 1990's – 100 more than the estimate produced by the *Hartford Courant* last fall. Furthermore, the current JCAHO administered monitoring system is a complete failure. For example, the GAO report concluded: "There is no comprehensive reporting system to track....injuries or deaths or the rates of restraint and seclusion use by facility." In fact, only 15 states have any systemic reporting system whatsoever.

S. 736 remedies this crisis situation in two ways. First, the legislation sets minimum restraint standards for federally financed residential treatment centers (RTCs) for children; the new HCFA rules don't. Establishing guidelines for RTCs is absolutely critical because the *Hartford Courant* – in its investigative series – estimated that 1/3 of restraint victims were children under age 17. Second, the Lieberman/Dodd bill establishes a thorough reporting system, including referral of death reports to appropriate state agencies, state attorney generals and Protection & Advocacy Agencies.

NMHA was disappointed that the Senate Finance Committee failed to attach S. 736 to the Tax Relief Extension Act; Congress must act now to stop these horrific deaths.

Sincerely,

Michael M.Faenza
President & CEO

Connecticut Children's
MEDICAL CENTER

Wednesday, May 12, 1999

The Honorable Joseph Lieberman
United States Senate
316 Hart Senate Office Building
Washington, DC 20510

Dear Senator Lieberman,

I am writing to confirm Connecticut Children's Medical Center's full support of your recently introduced bill, S 736-To amend titles XVII and XIX of the Social Security Act to ensure that individuals enjoy the right to be free from restraint and for other purposes. As Connecticut's only free-standing children's teaching hospital, and a facility which your bill would certainly have an impact on, I commend you for taking action to protect our nation's citizens who, at the present time, are most vulnerable.

The components of your bill which would allow physical restraints to be utilized only when prescribed by written order of a physician will be an effective means to placing careful checks on any maneuver which has a potential for harming patients. In addition, the reporting of 'sentinel events' to the oversight agencies identified in your bill will, I believe, serve as a catalyst toward the creation of more pro-active training programs on the use of physical restraints and alternatives to them, in affected healthcare facilities.

Thank you for all of your hard work on behalf of Connecticut citizens. If there is any way in which we here at Connecticut Children's may be of assistance, please do not hesitate to contact me. I look forward to seeing you here in the state, and hope you visit with us soon.

Sincerely,

Larry M. Gold
President and CEO

282 Washington Street Hartford, CT 06106 (860) 545-9000

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October 16, 1999

The Honorable Joseph I Lieberman
United States Senate
Washington, D.C., 20510-4601

Dear Senator Lieberman

I am writing on behalf of the American Association of Community Psychiatrists in support of S. 625, the Freedom From Restraint amendment. You and your staff have done a marvelous job of crafting a balanced and effective piece of legislation which addresses a very sensitive and complicated issue; that of the use of restraints in psychiatric facilities. We believe that your emphasis on reporting sentinel events is a correct approach consistent with current trends in medical quality assurance practice. We very much appreciate having had the opportunity to work with your staff in reviewing earlier drafts and are very gratified to see our suggestions reflected in the current draft. We believe that our patients, as well as all others in the hospital environment, are safer with the more expanded language regarding rule A under the Protection of Rights paragraph.

We know that in your state you have become acutely aware of the hazards of misuse of restraints through excellent discussions in your local periodicals. We also know that you have been very responsive to the anguish of members of NAMI over tragic mistakes in the use of restraints. The AACP has allied with NAMI over this issue. We feel that your amendments to the Social Security Act address the spirit of their concerns and provide our treatment community with a wise and thoughtful framework within which to practice.

We sincerely appreciate your leadership on this issue.

Sincerely,

Charles Huffine, MD, President
American Association of Community Psychiatrists

cc: Clarke Ross, NAMI

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REGIONAL VICE CHAIRS

Shelly Peterson
PRESIDENT OF AHCAE

David Seckman
INTERIM PRESIDENT

September 27, 1999

The Honorable Joseph I. Lieberman
The United States Senate
706 Hart Senate Office Building
Washington, DC 20510

Dear Senator Lieberman:

I am writing on behalf of the American Health Care Association (AHCA), a federation of 50 state associations representing 12,000 non-profit and for-profit nursing homes and assisted living facilities, to commend and support your efforts to control and regulate the use of restraints used by health care facilities. Thank you for the opportunity to talk with you last week about this bill and the Medicare issues facing nursing homes across the country.

Your bill, *The Freedom from Restraint Act of 1999*, (S. 736) would institute a restraint policy that would allow restraints to be imposed only to ensure the physical safety of the individual and only upon the written order of a physician. Nursing facilities have been operating for many years under a very similar restraint policy as a part of nursing home reforms contained in OBRA '87. Under this law, nursing homes decreased restraint usage from 40% in 1989 to 13% in 1998—a dramatic reduction. AHCA supports legislation that would protect vulnerable populations from the unnecessary and inappropriate use of restraints.

Another significant portion of your legislation addresses reporting by facilities regarding the use of restraints. Currently, nursing facilities and intermediate care facilities for the mentally retarded (ICF/MR) report restraint usage to the survey agency and other government agencies. Restraint usage is regulated by the survey agency through the survey process, and through utilizing tools such as the Minimum Data Set and quality indicators. Use of these tools and others, enables nursing facilities to track and monitor restraint usage and compare their usage with other facilities to determine areas for improvement.

We support your legislation as an important protection from unneeded restraint use for other populations in health care facilities. We also thank you for your leadership on this important legislation that ensures and safeguards the right to be free of restraints.

Sincerely,

Bruce Yarwood
Legislative Counsel

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THE AMERICAN HEALTH CARE ASSOCIATION IS A FEDERATION OF 50 AFFILIATED ASSOCIATIONS, REPRESENTING 12,000 NON-PROFIT AND FOR-PROFIT ASSISTED LIVING, NURSING FACILITY AND SUBACUTE PROVIDERS NATIONALLY.

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706 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Lieberman:

On behalf of the American Psychiatric Nurses Association (APNA), I would like to commend you for your work regarding the use of seclusion and restraint. APNA appreciates your leadership on this important issue. The APNA, with a membership of approximately 4,500, provides leadership to advance psychiatric-mental health nursing practice, improves mental health care for culturally diverse individuals, families, groups and communities and shapes health policy for the delivery of mental health services.

APNA would like to thank you for introducing legislation on the use of seclusion and restraint. Your legislation takes a giant step forward to establish and ensure much needed patient protections. APNA supports your proposal that would allow licensed independent practitioners to order seclusion or restraint. In addition, we applaud you for recognizing that seclusion or restraint should only be used "to ensure the physical safety of the individual or other individuals in the care or custody of the provider, staff member or others." APNA firmly believes that legislation is needed in order to ensure that seclusion or restraint is never used for purposes related to discipline or convenience and applied in emergency situations only. Again, we commend you for your leadership on this issue.

As the process moves forward, however, APNA would like to suggest the addition of provisions that would help strengthen your bill. To begin, APNA hopes that federal guidelines related to the use of seclusion and restraint can be extended to cover all patients -- in all settings. Secondly, APNA believes more detailed data reporting requirements should be established. Specifically, APNA would urge the recording and assessment of data containing (1) the number of incidents of seclusion, (2) the number of incidents of restraint, (3) the number of patients in seclusion, (4) the number of patients in restraint and (5) the average number of hours by incident, and by patient, in both seclusion and in restraint. This type of data would help the "benchmarking" process and assist health care professionals in their quest to provide the best patient care possible. Finally, APNA would encourage the inclusion of language pertaining to staff training. There is an urgent need to ensure that health professionals receive ongoing training on behavioral techniques to help avoid the use of seclusion or restraint and stress the safety of the patient and the providers of care.
We are hopeful that these and other considerations will be discussed during the scheduled hearing to be held by Senator Roth and subsequent meetings. As you know, the improper

use of seclusion and restraint is an issue that requires our immediate attention. Due to the unique perspective APNA members have on this issue, we have recently announced the formation of a Task Force on Seclusion and Restraint. One important goal of the Task Force will be to develop professional standards on this issue. Further, members of this body will represent the geographical and practice diversity of APNA. Task Force members include nurses who work in practice settings (such as public, private, academia); with different patient populations (such as adult, child/adolescent, geriatric), and who have specific roles (such as clinical nurse specialist, staff nurse, nurse practitioner, nurse manager). We are excited about the Task Force and will continue to provide you with information as developments occur.

Again, thank you for introducing legislation regarding the use of seclusion and restraint. APNA appreciates your dedication to mental health issues and looks forward to working with you during the remainder of the 106th Congress and beyond. Should you have any questions or require additional information, please do not hesitate to contact me or have your staff contact Rob Morrison of APNA Government Relations at (202) 857-5322.

Sincerely,

Jane Ryan

Jane Ryan, RN, MN, CNAA
President

Cc: Tim Gordon, Executive Director

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National Council for Community Behavioral Healthcare

October 21, 1999

The Honorable Joseph I. Lieberman
706 Hart Office Building
Washington, DC 20510

Dear Senator Lieberman:

The National Council for Community Behavioral Healthcare, and its membership which includes 800 community mental health and substance abuse provider organizations, advocates that behavioral health services must be based on the strengths and needs of the consumer. It is a fundamental principle that behavioral health treatment be administered with dignity and respect. Accordingly, the National Council shares the outrage of others in the behavioral health community concerning the reports of deaths and other serious incidents due to the inappropriate use of seclusion and/or restraints on people with behavioral health disorders many of which have been documented in the General Accounting Office's recent report "Improper Restraint or Seclusion Use Places People at Risk."

Therefore, it is with great pleasure that I report to you that the National Council supports the Freedom from Restraint Act, S. 736, which reforms seclusion and restraints of persons in psychiatric facilities.

As the legislative process advances, we look forward to continuing to work with you. We appreciate having had the opportunity to address the specific concerns of community providers operating crisis beds in rural, medically underserved areas. Our member organizations provide services to Medicaid and Medicare beneficiaries, as well as to the under- and uninsured. A majority of our center's charters require the provision of services regardless of ability to pay. Therefore limited funds and staffing abilities often make it impossible to have a psychiatrist (or other M.D) on the premises at all times. We are thankful that this legislation reflects these unique provider needs and allows supervision to be provided by other licensed and appropriately trained personnel such as psychiatric nurse practitioners.

We thank you for your leadership on the on these needed reforms and hope you will call on us to provide further assistance. The National Council is committed to seeing that this important legislation becomes law.

Very truly yours,

Pope M. Simmons
Vice President of Government Relations

NAPAS National Association of Protection & Advocacy Systems

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Executive Director

Curtis L. Decker, J.D.

October 20, 1999

Honorable Joseph Lieberman
United States Senate
706 Hart Senate Building
Washington, DC 20510

Dear Senator Lieberman:

I wish to express the continued support of the membership association for the nation's federally mandated disability rights system -- the Protection and Advocacy (P&A) System -- for the Freedom from Restraint Act of 1999 (S. 736). A fundamental mandate of the P&A System (the nation's largest provider of legal advocacy services to people with disabilities) is to investigate reports of abuse and neglect against persons with disabilities, including the misuse of restraint and seclusion. We believe that your proposed legislation will help develop a national strategy to minimize the deadly use of restraints and seclusion, and is critically necessary, notwithstanding the recent issuance of regulations on this subject by the Health Care Financing Administration (HCFA).

We strongly support the minimum standards contained in the bill on the use of restraints and seclusion which – unlike those contained in the HCFA regulations (which apply only to hospitals) – are broadly applicable to service providers who receive Medicaid or Medicare. And, we support as well the bill's requirement that a broad range of restraint-related deaths of persons with mental illness be reported to P&As and other oversight agencies so that appropriate investigations and corrective action may occur. In contrast to this requirement, the HCFA regulations do not establish a clear requirement for reporting of deaths to P&As and other outside investigative agencies (other than HCFA) for follow up. The preamble to the rules (but not the regulations themselves) merely indicate HCFA's intent to share with P&As (in some unspecified manner) hospital reports of deaths.

It is critical that clear, enforceable legislative requirements for reporting restraint-related deaths to P&As be established. Once the P&A receives these reports required under this bill, their trained investigators and legal staff can determine which deaths may be due to the misuse of restraint, and can take appropriate corrective actions (including negotiation or litigation to reform facility practices) to ensure that these abuses do not occur in the future.

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Website: http://www.protectionandadvocacy.com
E-Mail: napas@vipmail.earthlink.net

NAPAS is eager to provide any assistance needed to promote passage of this legislation.

Sincerely,

Curtis L. Decker
Executive Director

BAZELON CENTER FOR MENTAL HEALTH LAW

Civil Rights and Human Dignity

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Robert Bernstein, Ph.D.

October 20, 1999

The Honorable Joseph Lieberman
United States Senate
Washington, DC. 20510

Dear Senator Lieberman:

On behalf of The Bazelon Center for Mental Health Law—the leading national legal-advocacy organization representing people with mental disabilities—I am writing to express our continued support of S. 736, " The Freedom from Restraint Act of 1999." We believe enacting this legislation is critical to appropriately addressing the deaths, serious injuries, abuse and trauma that have resulted from the use of restraints and seclusion.

Although we commend the Health Care Financing Administration (HCFA) for promulgating regulations on restraint and seclusion for Medicaid and Medicare funded hospitals this summer, we strongly believe these rules should be considered a first step to improving the quality of care for this vulnerable population. It is clear that Congress must pass legislation to further protect children and adults in other psychiatric treatment settings, such as residential treatment centers, and establish important reporting requirements.

S. 736 would build upon the HCFA rules. Under your legislation, reporting would be extended to state protection and advocacy agencies who have the authority to investigate reports of these tragedies. Protection would also be extended to residential treatment centers, where many of the child deaths by restraint occurred. The recent General Accounting Office (GAO) report on restraint use documented this crisis and also highlighted the lack of comprehensive reporting. We are confident that S. 736 is the next step to meeting this needed federal protection.

The Bazelon Center is committed to working with you to enact legislation.

Sincerely,

Robert Bernstein, Ph.D.
Executive Director

1101 Fifteenth Street NW, Suite 1212, Washington DC 20005-5002, 202/467-5730, TDD: 202/467-4232, fax: 202/223-0409 http://www.bazelon.org, e-mail: hrl660@handsnet.org

October 18, 1999

Honorable Joseph Lieberman
U.S. Senator, Connecticut
706 Hart Senate Building
Washington, DC 20215

Attention: Ned McCulloch

Dear Senator Lieberman:

NAMI – the National Alliance for the Mentally Ill – an organization of 210,000 consumer and family members who are directly affected by severe mental illness, continues to endorse and call for enactment of your legislation, S. 736, the "Freedom From Restraint Act of 1999."

On the first day of this month the U.S. General Accounting Office (GAO) documented and affirmed that deaths and serious injuries resulting from restraints applied in psychiatric treatment facilities continue nationwide. While the Health Care Financing Administration (HCFA) interim final Medicare and Medicaid conditions of participation (COP) are helpful, they are incomplete, they do not contain important reporting procedures, and, as regulations, can be changed on the whim of any change in administration.

The HCFA rules cover only hospitals and the only reports are of deaths submitted to HCFA regional offices. Two important advocate premises, largely contained in S. 736, are that a single national standard should govern restraint use in all federally assisted psychiatric treatment facilities and that any death or serious injury must be reported to state-based legal entities which have the authority to investigate the circumstances of these deaths and injuries. Further, given the predominance of such deaths and serious injuries and the absence of any clinical evidence-base for the use of restraints, a legislative basis is needed.

NAMI stands ready to assist you enact such legislation.

Sincerely,

E. Clarke Ross, D.P.A.
Deputy Executive Director for Public Policy
703-312-7894 clarke@nami.org

THE FEDERATION OF FAMILIES
FOR
CHILDREN'S MENTAL HEALTH

October 18, 1999

Honorable Joseph Lieberman
U.S. Senator, Connecticut
706 Hart Senate Building
Washington, Dc 20215

Dear Senator Lieberman:

The Federation of Families for Children's Mental Health is the nation's advocate for children's mental health. We are a network of family-run organizations in every state and our membership includes thousands of families of all colors and from all walks of life who love and care for children with emotional, behavioral, or mental disorders.

Our children are directly affected by the use of physical and chemical and restraints and isolation or seclusion – some on a daily basis – in public and private schools, day and residential treatment centers, hospitals, specialized foster care and group homes, and juvenile detention and correctional facilities. Yet, there is no evidence that these practices are therapeutic in any way and there is ample documentation of the danger they pose and the death they have caused.

Existing state and federal (HCFA) licensing requirements and practices of these facilities provide children and youth with inconsistent and insufficient protection from the harmful effects of seclusion and restraints that have been documented by the General Accounting Office's recent report "Improper Restraint or Seclusion Use Places People at Risk." Furthermore, there is no uniform format or requirement for reporting the use of seclusion and restraint, its frequency, duration, the precipitating events, or its impact on the child or youth. Even the deaths that occur when children are under the influence of seclusion or restraints are not systematically reported.

The Federation of Families for Children's Mental Health contends that the safety and health of our children must be protected and must over ride the self-interest of facilities and institutions (and the professionals who work in them). Please take a moment to look over our position statement on seclusion and restraint which is enclosed.

Only Congressional action, such as S.736, can assure a national policy is established that restricts the use of seclusion and restraint to defined emergency situations and requires their use to be reported to public officials and the child's family. The Federation of Families for Children's Mental Health encourages you to continue pushing for legislation that would achieve these ends. We are ready to help you enact such legislation.

Sincerely,
Trina W. Osher
Coordinator of Policy and Research

1021 Prince Street • Alexandria, Virginia 22314-2971 • 703/684-7710

Joint Commission
on Accreditation of Healthcare Organizations

March 24, 1999

The Honorable Christopher J. Dodd
444 Russell Senate Office Building
Delaware and Constitution Avenues, N.E.
Washington, D.C. 20510-0702

The Honorable Joseph I. Lieberman
706 Hart Senate Office Building
Second Street and Constitution Avenue, N.E.
Washington, D.C. 20510-0703

Dear Senators Lieberman and Dodd:

The Joint Commission commends your leadership in seeking to reduce the number of restraint-related deaths of individuals under treatment for psychiatric or psychological conditions. The occurrence of restraint-related deaths presents a most serious and complex set of issues for all of us in health care and for public policy-makers. Meaningful solutions will clearly require significant efforts by all interested parties. Such efforts must be of the highest priority, for the issues involved go to the very heart of patient rights and patient safety.

The Joint Commission views many of the provisions contained in your bill as critical elements of a framework for addressing both restraint-related deaths and other sentinel events that occur in the delivery of health care. We support the mandatory reporting and disclosure of deaths related to the use of restraints as the essential foundation for determining the magnitude of the problem and for identifying the causal factors that have contributed to the devastating occurrences portrayed in the recent *Hartford Courant* series.

However, as your bill recognizes, reporting is only the first step towards substantive improvements in protecting patient rights and improving patient safety. The critical next step is to elucidate through careful analysis the systems problems that frequently underlie sentinel events. This in-depth root cause analysis which should immediately follow any sentinel event is the vehicle that permits the involved health care organization to fully understand what happened, why it happened and what steps must be taken to reduce the likelihood of any future recurrence. We strongly agree with your premise that the confidentiality of this root cause analysis must be protected in order to foster and assure full exploration and understanding of all potential contributing factors. By establishing a non-punitive environment in which organizations can

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Member Organizations
American College of Physicians
American College of Surgeons
American Dental Association
American Hospital Association
American Medical Association

examine their mistakes honestly, this bill will both foster better and safer care in organizations where sentinel events have occurred, and create the opportunity for sharing lifesaving "lessons learned" with like health care organizations.

Again, we the appreciate the opportunity to work with you and others as your legislation moves forward. Congratulations on your leadership on this matter.

Sincerely,

Dennis S. O'Leary, M.D.

Dennis S. O'Leary, M.D.
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

MAR 2 4 1999

The Honorable Joseph I. Lieberman
United States Senate
Washington, D.C. 20510

Dear Senator Lieberman:

I am writing in strong support of your efforts to provide additional Federal oversight to prevent inappropriate seclusion and restraint practices in mental health settings. The President, Secretary Shalala, and I share your concern over the recent reports of children who died after being inappropriately restrained, and we applaud your efforts to protect all hospital patients from harm associated with the use of seclusion and restraints. We look forward to working with you on the specifics of the legislation as it moves forward.

I would also like to take this opportunity to update you on the Administration's recent efforts to protect children and other hospital patients from harm associated with the inappropriate use of restraints. As you may know, in the Notice of Proposed Rulemaking (NPRM) for the new Medicare hospital Conditions of Participation (CoP), HCFA proposed a CoP to address patients' rights. Within this CoP, HCFA proposed standards restricting for the first time, the use of restraints in hospital settings. The Medicare hospital CoPs apply to all patients in hospitals who participate in the Medicare program, therefore, these rights extend beyond the Medicare population in these facilities. In addition, the hospital CoPs apply to Medicaid hospitals as well.

Because of the importance of this issue to the health and safety of patients, we plan to carve out the "Patients Rights" section (which addresses the seclusion/restraint issue) of the CoP from the larger hospital conditions of participation regulation so that we can publish the standard in final by late summer. By carving out this section, HCFA will be able to move more quickly to hold all hospitals that participate in Medicare and Medicaid accountable for the inappropriate use of seclusion and restraints. The proposed Patient Rights CoP will apply to all participating hospitals, including acute, psychiatric, rehabilitation, long-term, children's, and alcohol-drug hospitals.

In addition to our efforts with hospitals, HCFA already has regulations restricting the use of restraints in settings including intermediate care facilities for the mentally retarded (ICFs-MR) and nursing facilities. In addition, the Clinton Administration has made improving the quality of nursing home care and oversight a top priority. Last July, the President announced a broad initiative to strengthen the enforcement of our nursing home regulations, which we published in 1995.

The Honorable Joseph I. Lieberman

In addition to HCFA's efforts, a number of other federal agencies are increasing attention to inappropriate seclusion and restraint practices. Most notably, the Center for Mental Health Services (CMHS) of the Substance Abuse and Mental Health Services (SAMHSA) Administration within the U.S. Department of Health and Human Services provides funds to state protection and advocacy systems. These systems, present in each state, have a strong record of addressing and resolving consumer complaints related to the misuse of seclusion and restraint. Moreover, HCFA staff are actively participating with CMHS in the development and implementation of an action plan that will continue to address problems with the misuse of seclusion and restraints in our nation's health care facilities.

Your legislation will add to these efforts by expanding the scope of this policy to patients in settings that HCFA does not have the authority to regulate such as residential treatment centers for children and congregate care services under a waiver authorized under section 1915(c). Your bill also emphasizes the need for more accurate and timely reporting through the establishment or designation of sentinel events restraint database. We look forward to working with you and with your staff on this approach.

The President, Secretary Shalala, and I strongly support your interest and efforts and those of your colleagues to prevent the inappropriate and dangerous use of restraints in mental health settings, and I am confident that we can work together to protect the children and other vulnerable patients who are currently at risk.

Sincerely,

Nancy-Ann Min DeParle
Administrator

370 Linwood Street
New Britain, CT 06052
(860) 224-9113
FAX:(860) 826-1739
www.klingberg.com

March 24, 1999

U.S. Senator Joseph Lieberman
706 Senate Hart Building
Washington, D.C. 20510

Dear Sen. Lieberman:

As a provider of mental health services to Connecticut's children and families, Klingberg Family Centers applauds your efforts to ensure the safety and wellbeing of individuals being cared for in institutional settings. We trust that The Freedom From Restraint Act of 1999 will result in agencies adopting policies that protect both their patients and those that are caring for them.

Through our years of work with children and families, we recognize the value of regularly taking a critical look at how best to serve others. The people we are striving to help are facing complex problems which can be responded to with a wide range of therapeutic interventions. Physical interventions conducted in a spirit of concern for the client and others can successfully calm an individual who needs help in gaining control of their behavior. In addition to establishing regulations and clearly defining the boundaries in the use of physical restraint, it is critically important to thoroughly train staff members in order to equip them to provide the best treatment to those in their care.

We certainly agree that the appropriate and therapeutic use of physical restraint deserves thoughtful consideration and we would hope that one day we might eliminate the need for this level of intervention altogether. In our commitment to developing and adhering to best practices, Klingberg Family Centers would welcome the opportunity to assist you in exploring this issue further. We would be happy to consult with both the National Association of Psychiatric Treatment Centers for Children and the Child Welfare League of America to find other examples of how facilities across our nation are addressing this issue with competency and caring. Please feel free to contact me at (860) 224-9113 if we can be of any help.

Sincerely,

Rosemarie A. Burton

Rosemarie A. Burton
President

YALE UNIVERSITY

Donald J. Cohen, M.D.
Director, Child Study Center
Irving B. Harris Professor of
Child Psychiatry, Pediatrics
and Psychology
Yale University School of Medicine

Chief, Child Psychiatry
Children's Hospital at
Yale-New Haven

March 23, 1999

The Honorable Joseph Lieberman
United States Senate
Washington, D.C.

Dear Senator Lieberman,

We are writing to provide support for the Freedom From Restraint Act of 1999 and to applaud your efforts to improve the quality of care provided to individuals with serious psychiatric disorders.

The scope and burden of serious psychiatric disorders in children and adolescents is enormous. In the United States and worldwide, up to 8% of all children have serious emotional, development and behavioral disorders. Only a small proportion of these children requires treatment in specialized, inpatient hospital settings. Those who require inpatient care generally suffer from the most severe and broad-based disturbances that affect their social, emotional, intellectual and behavioral development and functioning. These complicated patients require thorough diagnostic assessment and multi-modal therapy. Some of these children present difficulties which are a threat to their own physical safety or to the physical safety of other patients and clinicians. This type of clinical situation requires thorough, specialized assessment to define an appropriate treatment plan to help the child regain control and to prevent any harm to himself/herself or others. Such a plan may include careful observation, more intensive or one-on-one staffing, the utilization of behavioral techniques that allow the child to calm down and reorganize, the judicious use of medication, analysis of the precipitants and management of outbursts, and the use of time-out and quiet rooms.

On occasion, in the context of a comprehensive treatment/intervention program, it may at times also be necessary to use physical restraints to protect the child or others from imminent harm. When they are used, the methods for applying the restraint, including the use of any mechanical devices, must be employed only by individuals who are specially trained. At times, restraints must be used to deal with an urgent situation. When restraints are used with children or adolescents, it is essential that certain conditions are met: that the danger of harm is real and imminent, the restraints must be prescribed by a physician, the restraint methods must be fully documented and approved, the clinicians using the methods must be well trained in a documented training program, the restraint use must be carefully monitored, the restraints are discontinued as soon as the danger for harm is no longer imminent, and the entire process must be accurately reported. When possible, it is important to obtain informed consent from the guardians of the child/adolescent before any restraint method is used. In cases of emergency, to protect a child or others, the parents/guardians should be notified as soon as possible and provided with a detailed description and, if feasible, observation of the method of restraint. Following each use of restraints, it should be clinically evaluated by the full clinical team to determine if other approaches might have been used or should be used in the future.

Yale Child Study Center 230 South Frontage Road P.O. Box 207900 New Haven, CT 06520-7900
Telephone: 203 785-5759 Fax: 203 785-7402 E-mail: DONALD.COHEN@YALE.EDU

We believe that the Freedom From Restraint Act of 1999 is a movement in the right direction. It will increase awareness of the importance of providing optimal care to individuals with the most serious psychiatric disorders who are hospitalized for evaluation and treatment. The Act clearly defines that the purpose of restraints is for the safety of the individual or other individuals and the Act helps assure that restraints will be used only with suitable medical oversight. We also appreciate the importance of detailed assessment of sentinel events. We believe that the Act will help in the process of improving clinical care of children and adolescents, as well as adults with psychiatric disorders.

There are rapid advances in knowledge about the causes and treatment of psychiatric disorders of children, adolescents, and adults. We can look forward to further improvements in the prevention of disorders and their effective amelioration. Hopefully, this knowledge will reduce the burden of suffering for individuals and their families, and will help reduce the need for hospitalization and restraints. However, at the same time, it is critically important to improve the current care that individuals in hospital are receiving. To do this will require varied types of efforts for training of clinicians and staff, funding for services, and improvement in settings of care. The Freedom From Restraint Act highlights one, specific issue involved in providing high quality, compassionate care. As child and adolescent psychiatrists, we are very pleased by your concern and by the leadership that you have taken to help assure that individuals with psychiatric disturbances will receive the best treatment possible.

Sincerely,

Donald J. Cohen, M.D.
Irving B. Harris Professor of
Child Psychiatry, Pediatrics and Psychology
Director, Yale Child Study Center

John Schowalter, M.D.
John Schowalter
A.J. Solnit Professor of
Child Psychiatry & Pediatrics
Clinical Director, Yale Child Study Center

Joseph Woolston
Joseph Woolston, M.D.
Associate Professor of Child Psychiatry
Medical Director of InPatient Services of
Child Psychiatry at Yale New Haven Hospital

Community Addiction Services of Indiana, Inc.

CASI Outpatient Services
1040 East New York Street
Indianapolis, IN 46202
Phone Number: (317) 633-8240 Fax: (317) 633-8153

August 10, 1999

Senator Joseph Lieberman
U.S. House of Representatives
Washington, DC 20515

Dear Senator Lieberman:

I am in full support of significant restrictions on the use of physical restraint proposed in S736.

I have operated an adolescent residential addictions treatment program for the last 15 years. The participants in our program are mostly adjudicated juvenile delinquents with low income, long arrest records, histories of assault and combative behavior from dysfunctional homes.

Since opening in 1985 we have not trained any staff in the use of any restraint method. Conversely, we train all staff in early de-escalation, avoidance of "power struggles" and clear and consistent consequences. In addition, any physically aggressive contact is dealt with clearly and quickly and in any situation that appears to be dangerous, our staff calls the police.

We have and will continue to assist participants to file assault charges against other participants an replace staff that display aggressive behavior.

As a result of our procedures from the beginning, the community culture is non-violent. We have never had a serious assault of any staff person from the participants and participant to participant issues have been minor, rare and dealt with by law enforcement. The consequences of violent behavior is clear and real life consequences occur.

If our agency can build a non-violent community, so can others. However, it will require a significant shift in philosophy for many "care" providers.

Sincerely,

Thomas W. Cox
President
Community Addiction Services of Indiana, Inc.

PREPARED STATEMENT OF CHARLES E. RIORDAN, M.D.

Mr. Chairman, I am Charles E. Riordan, M.D. I am Vice President for Medical Affairs of Saint Raphael Health Care System in New Haven, Connecticut, Clinical Professor of Psychiatry at Yale University School of Medicine, and Attending Psychiatrist at Yale-New Haven Hospital.

I am a Fellow of the American Psychiatric Association (APA), and I am also Chair of the APA Committee on Standards and Surveys, a member of the APA Council on Quality Improvement, and the APA Representative to the Joint Commission on Accreditation of Healthcare Organization's (JCAHO) Professional and Technical Advisory Committee (PTAC) for Hospital Accreditation Program.

My testimony today is presented on behalf of the American Psychiatric Association. APA is the national medical specialty society representing more than 42,000 psychiatric physicians nationwide. Our members practice in every setting, including solo private practice, group practice, inpatient units, residential treatment facilities, state hospitals, the VA and military health care systems, and community mental health centers. We are also academicians, researchers, and part of the nation's public health care system. In short, psychiatrists are on the front line of America's health care system, and particularly in those parts of the system dedicated to the treatment of patients with psychiatric disorders.

My testimony will address the General Accounting Office's recent report on Seclusion and Restraint, as well as the clinical impact of various legislative and regulatory proposals currently pending before Congress and in the Executive Branch. These include legislation sponsored by Senators Dodd and Lieberman, and the interim final rule on Medicare and Medicaid hospital conditions of participation published in the Federal Register on July 2 and in force as of August 2.

First and foremost, APA commends you and the Finance Committee for holding this hearing on the use of seclusion and restraint. It is absolutely vital that public hearings provide an opportunity for clinicians, Members of Congress, patient advocates, and patients/consumers to sit down together and discuss vital patient care issues. It is our hope that a dispassionate examination of restraint (and of seclusion), including deaths and serious injuries allegedly caused by improper use of restraint or seclusion will further APA's overarching objective of ensuring the provision of all medically necessary treatment of psychiatric patients in an environment that is safe and humane for patients and for staff.

1. The Current Context:

APA shares the concern of Congress, HCFA, and patient advocates that special care be taken when patients are placed in seclusion or restraint for psychiatric purposes. We agree that death should never be a direct result of being placed in seclusion or restraint. We concur that such interventions should be taken with the utmost care and concern for patient safety as well as the safety of staff and others, should be viewed as two of numerous alternative interventions, and should be undertaken in circumstances in which a physician determines that the patient's clinical condition warrants the intervention. Likewise, we agree that seclusion and restraint should be terminated at the earliest opportunity when the specific threat to the safety of patient, staff, or others has passed and other alternatives are clinically appropriate.

The spate of recent news stories (e.g., Hartford Courant, Fox Files, 60 Minutes) has focused public attention on the care of psychiatric patients in the inpatient or

residential setting. The stories in the press are lamentable, and we reiterate that seclusion or restraint should not cause deaths. However, we believe that efforts to increase the safety of seclusion and restraint and to decrease deaths caused by these interventions must be based on a clear understanding of the causes of deaths and serious injury, and particularly of those legislative or regulatory actions that can be taken to directly achieve the desired results.

We caution that precipitous action prior to a full examination of the factors leading to safety problems may have unintended negative consequences without any improvement in safety. That is, unfortunately, where we seem to be heading at the present time. In the space of the past few months, we have seen:

- A GAO Report
- Two Senate bills, one of which is pending Senate consideration as an amendment to the SAMHSA reauthorization
- Two House bills
- Two Senate hearings
- A series of JCAHO public field hearings and internal commission meetings
- Drafting of new JCAHO standards now pending field testing
- Sweeping new federal regulations

All of these actions are occurring independent of each other, yet some of them are at least potentially contradictory. While there are many problems with the HCFA rules, the likely implementation of the rules renders pending federal legislation largely redundant. The HCFA rules themselves are fraught with contradictions, complexities, and lack of vital definitions.

Standards are proposed and supplanted, while APA members are literally unable to determine what rules they are supposed to follow and to what standard they will now be held. Is the HCFA rule now in force? Are there instructions on compliance? Do surveyors have final interpretive guidelines? Will the standards change? And, most important, what is the likely impact on patient care and patient access to care? To date, none of these questions have been answered.

It is vital to note that the incidence of use of seclusion and restraint, and particularly deaths or serious injuries caused by such use, cannot be viewed in the abstract but must be seen in the clinical context in which treatment occurs.

Psychiatric facilities today face unprecedented challenges. Whether by managed care or by more traditional health insurance, there is great pressure not to admit patients to the more expensive inpatient setting unless there is simply no alternative. That means that the patients we see in these settings are more seriously ill than ever before. Many—perhaps most—are in the acute stages of their illness, and their underlying illnesses are more likely to be severe.

At the same time, psychiatric facilities and the physicians and other health professionals who work in them are under greater budgetary pressure than ever. For example, the Balanced Budget Act of 1997 reduced payments to so-called "TEFRA" hospitals (i.e., those hospitals—including psychiatric hospitals—that are exempt from the Prospective Payment System) by $5 billion.

So disadvantageous was this reduction that representatives of the psychiatric hospital industry have decided to pursue PPS coverage, now advancing as part of the Medicare BBA'97 "fix" bill in the House. Likewise, payments to psychiatrists and other health staff are constantly being squeezed by insurers, whether Medicare or private.

Bluntly, psychiatrists and other health professionals and the facilities in which we work are being asked to do more than ever for patients who are more acutely ill than ever before with less resources. It is particularly disturbing to APA that discussion of resource commitment has, thus far, been entirely absent from the public discourse.

2. APA's Efforts:

APA has a long-standing record of involvement with the development of general guidelines and principles for the use of seclusion and restraint. For example, the Report of the Task Force on Seclusion and Restraint (1984, amended 1992) provides a very thorough overview of the practices in seclusion and restraint as they are used in the treatment and management of violent and disruptive behaviors in the treatment setting. The report also reviewed alternatives to the use of physical controls, and it includes a very helpful discussion of indications, contraindications, and emergency use of seclusion and restraint. We are submitting a copy of the Task Force Report for the record.

In response to APA's concern about the patient care implications of the Courant series, APA Medical Director Steven M. Mirin, M.D. directed that APA convene a panel of experts first to develop a statement of general principles on seclusion and restraint and, second, to develop clinical best practices standards.

The discussions, which included presentations by representatives of patient advocacy groups, led to the publication of a Resource Guide on Seclusion and Restraint that has been widely distributed to the field. The Resource Guide is attached to this written testimony. A careful review of these and other documents shows that there is more agreement than disagreement on general principles governing the use of seclusion and restraint between physicians and most patient advocates.

Here is a brief summary of the key points of our Resource Guide:

- Seclusion and restraint are interventions that carry a degree of risk. They may be used where, in the clinical judgement of medical staff, less restrictive interventions are inadequate.
- Seclusion and restraint may be indicated (a) to prevent harm to the patient or other persons including other patients, family members, and staff, and (b) to ensure a safe treatment environment.
- A physician should write seclusion and restraint orders.
- The physician should examine the patient and ensure appropriate monitoring and care throughout the episode.
- Staff should be thoroughly trained and have demonstrated competence in the application of safe and effective techniques for implementing seclusion and restraint.
- Patients should be removed from seclusion or restraint when, in the physician's judgement, the patient no longer poses a threat to himself/herself, other patients, family members, or staff.
- Use of seclusion and restraint should be minimized to the extent that is consistent with safe and effective psychiatric care and the specific clinical needs of the patient. Likewise, staff should be trained in the use of alternative interventions that may reduce the need for seclusion and restraint. Facilities should engage in a continuous quality improvement program that seeks to minimize the use of seclusion and restraint consistent with good standards of clinical practice and the needs of individual patients.
- Death and serious injury from interventions involving seclusion and restraint must be reviewed internally. In addition to internal review, external review by, or subject to, an accrediting organization may also be required, with appropriate legal and confidentiality protections.

In brief, APA has always sought the best possible care for our patients and is prepared to work with the Congress, HCFA, patient advocates, and the hospital industry to ensure that our patients are accorded the best possible care conforming to best practices as developed through rigorous and impartial clinical review.

3. The GAO Report:

Let me address the recent report from the General Accounting Office that prompted this hearing (Mental Health: Improper Restraint or Seclusion Use Places People at Risk; GAO/HEHS–99–176, September 1999). I should note that APA medical staff were interviewed by the GAO principal investigators, and we provided GAO with the names of expert clinicians for further consultations. The GAO report as you know essentially concludes that more needs to be known in order to assess the full impact of deaths or serious injuries attributable to seclusion or restraint. Further, GAO notes that successful strategies for reducing seclusion and restraint include required reporting, adequate staffing levels, effective staff training, and clear facility guidelines.

The report recommends that patients be accorded the rights "to be free from any physical or chemical restraints or seclusion imposed for the purposes of coercion, discipline, or staff convenience . . ." that deaths or serious injuries be reported to the state licensing authority and the appropriate protection and advocacy system, that facilities maintain records to document use of seclusion or restraint, and that staff be trained to ensure safe use of these interventions as well as alternatives.

There is little to debate about the GAO's findings. We agree with the implicit finding that more needs to be known about national incidence of deaths or serious injuries that are attributable to seclusion or restraint. While we do not agree that deaths or serious injuries should be reported to the P&As, we do concur with the recommendation that deaths be uniformly reported to an appropriate state or federal agency. We suggest that should be either the state licensing agency or the Secretary of Health and Human Services.

We wholeheartedly concur with the recommendation that staffing levels and staff training be sufficient to ensure the safe and effective use of seclusion and restraint. Likewise, we believe staff should be thoroughly trained in de-escalation techniques and other alternatives to seclusion and restraint.

While the GAO report is helpful, it essentially states what is—and is not—now known. We believe it would have been helpful if GAO had addressed broader questions. These include the following:

- How many psychiatric patients were in inpatient or residential treatment settings in the period examined by GAO?
- How many of those patients were secluded or restrained?
- For how long were patients secluded or restrained?
- Were the facilities JCAHO accredited?
- State licensed?
- What post-event root cause analyses took place?
- What were the results of those analyses?
- What corrective actions were undertaken by the facilities?
- What is the incidence of patient-to-patient assaults during this period?
- What is the incidence of patient-to-staff assaults during this period?

In summary, while we find little to question in the GAO report, the report itself raises many additional questions we would like to see answered.

4. Pending Legislation:

The federal response to the allegations of improper use of seclusion and restraint have taken two tracks. Senators Dodd and Lieberman have introduced legislation (S. 750 and S. 736, respectively) that seek to limit the use of seclusion and restraint in facilities receiving federal funds (Dodd) or that serve Medicare or Medicaid patients (Lieberman). While the two bills are quite different, they are generally viewed as complementary. Similar legislation has been introduced in the House.

Let me address these in turn. APA worked closely with Senators Dodd and Frist to craft compromise language that was added to Senator Frist's bill to reauthorize the Substance Abuse and Mental Health Services Administration. The Dodd language, as amended, is a relatively straightforward and focused effort to craft basic standards for the use of seclusion and restraint and reporting of deaths. We commend Senator Dodd and his staff for their willingness to work with us to resolve many of the concerns we had about the original bill language as introduced.

We still have some technical issues with the language as adopted by the Committee on Health, Education, Labor and Pensions. For example, the language includes the use of the term "chemical restraint" which we strongly oppose as imprecise, inaccurate and pejorative. The issue is not "chemical restraints" but rather the inappropriate use of psychotropic medications for purposes of convenience or discipline. HCFA recognized this in its July 2 interim final rule, referring to restraints as either a physical restraint or a drug used as a restraint, not to a "chemical restraint." The reference in the Dodd language is, we believe, the result of miscommunication rather than policy, and we hope both Senators Dodd and Frist will support a technical amendment to clarify the meaning of this language.

The Dodd language commendably recognizes that restraints or seclusion may be required to protect staff as well as patients, but it fails to acknowledge that there will inevitably be circumstances short of physical safety where it is appropriate and necessary to seclude or restrain a patient.

The Lieberman bill is much more problematic. We are very pleased that Senator Lieberman's latest draft (crafted as a floor amendment) finally acknowledges that staff safety is a legitimate issue, rather than barring the use of seclusion or restraint in any circumstances other than the physical safety of the patient as in the bill as introduced. Still, the language is highly problematic from the APA's perspective.

For example, the Lieberman language:

- Includes the term "chemical restraint," which we oppose.
- Misuses the term "sentinel event" in a manner that is inconsistent with the JCAHO standards from which it is apparently drawn.
- Includes within the definition of sentinel event "serious physical or psychological injury" without a definition of these terms.
- Assumes that all sentinel events require a plan of correction when in fact an analysis may conclude that the facility did nothing wrong.
- Establishes a burdensome and duplicative reporting requirement.

Let me highlight a key problem. The Lieberman amendment says that a sentinel event is "an unexpected occurrence involving an individual in the care of a provider of services for treatment for a psychiatric or psychological illness that results in death or serious physical or psychological injury that is unrelated to the natural course of the individual's illness or underlying condition." The lack of precision of this definition creates potentially insurmountable problems for facilities.

APA, for example, has held meetings with public advocates who state unequivocally that the use of seclusion or restraint is both a treatment failure and per se

traumatizing—and hence injurious—to patients. By this standard—and potentially under the vague definitions in the Lieberman draft—any use of restraint or seclusion could be held to be psychologically injurious and thus a sentinel event subject to the bill's reporting requirements.

In contrast, JCAHO's current standard for a sentinel event is that "the event has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition." This is a much more precise description of the event.

Likewise, a key part of the JCAHO standard is the fact that the phrase "major permanent loss of function" is defined as "sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life change." This is significantly clearer than the Lieberman definition and avoids the obvious problems.

If the Committee intends to move forward with legislation, given the problems with the Lieberman bill, we strongly recommend that the Dodd amendment to the SAMHSA reauthorization—as amended by our technical correction to delete the use of term "chemical restraint"—be used.

5. The July 2 HCFA Interim Final Rule:

On the regulatory front, the U.S. Health Care Financing Administration published an interim final rule (with comment) in the July 2 Federal Register that establishes a new Medicare and Medicaid hospital condition of participation that sharply restricts the use of seclusion and restraint. I am submitting as an attachment APA's full comments to HCFA, since they are too detailed to discuss here.

As you know, on July 2 HCFA released as an interim final rule with comment a new Medicare and Medicaid hospital condition of participation, establishing a new Patients Rights condition of participation. I note for the record that the proposed rule on Medicare conditions of participation was published in December, 1997, with no reference to seclusion and restraint. Yet HCFA published this sweeping new standard as an interim final rule, making it effective on August 2, even though HCFA held the rule open for additional comments until August 31. Thus, technically, the new rule was in force even before the comment period closed. We are still waiting for a final rule. Meanwhile, facilities appear to be subject to the new standard.

In brief, the rule would sharply limit permitted use of seclusion and restraint of psychiatric patients; require a face-to-face assessment of the patient "within 1 hour after the initiation of this intervention;" require consultation with the patient's "treating physician" as soon as possible; limit the total effective duration of the initial order to 24 hours; require a new face-to-face assessment before a new order can be written; require renewal of the original written order every 4 hours for adults, 2 hours for adolescents and older children, and 1 hour for younger children; and require ongoing education of staff.

Regardless of what one makes of the specific provisions of the rule, there should be no doubt that it represents an unprecedented change in standards of care and dictates, to an extraordinary degree, specific clinical standards of care. Portions of this rule are an attempt to specify medical practice. The rule specifically defines the circumstances under which seclusion or restraint for behavioral purposes may be ordered, how long such orders may be in effect, and what standards of care must be exercised when a patient is placed in seclusion or restraints or both.

Mr. Chairman, the specificity of the standards are an inappropriate attempt to practice medicine and are an ineffective substitute for the individual clinical judgment of the physician. We acknowledge that these interventions should be used as sparingly as possible, but it does not follow that an arbitrary and untested Federal standard, particularly as laid out in the rule, is an appropriate response.

Does HCFA propose to require orthopedic specialists to set fractures within an hour? Oncologists to initiate chemotherapy within an hour? Surgeons to remove an appendix within an hour? Cardiologists to visit patients within an hour? No, because HCFA recognizes that these and countless other decisions about what to do and when to do it are best made by the individual physician considering all relevant aspects of the potential medical requirements for his or her patient, even when the mortality rate for patients hospitalized for other illnesses is clearly higher than for psychiatric patients. Why then should the decision about when and under what circumstances an individual patient should or should not be secluded or restrained be treated differently?

With respect to the specific requirements, the 1-hour rule is simply unsustainable. While we absolutely agree that the physician should be advised of the initiation of restraints or seclusion as soon as possible, and while we believe that the decision to order these interventions should flow from the physician, there is no consensus—

and we believe no evidence—that a 1 hour face-to-face physician assessment is warranted.

Compliance with the 1-hour rule will impose significant burdens on both physicians and the hospitals providing patient care. While the 1 hour rule may be feasible for hospitals with physicians in residence and on grounds 24 hours a day, 7 days a week, or for teaching hospitals that may be able to use residents to meet the requirement, it is not feasible for many smaller hospitals, freestanding psychiatric hospitals, and rural hospitals.

HCFA's assertions that its rule will not pose and undue burden to hospitals or have an appreciable cost impact is utterly specious, and this Committee should demand the details of the internal analysis that led HCFA to make this statement in the preamble to the rule. The rule will require hospitals to substantially increase the physical coverage of physicians as well as to take new steps to train staff. It will also require facilities to staff up to meet the higher intensity of services that will inevitably be required. All of this will add appreciably to hospital burdens and hospital costs.

What is particularly frustrating is that these mandates are completely out of sync with HCFA payment policies. For example, the effect of the rule seems likely to require multiple physician interventions and assessments of the same patient in the same 24-hour period. Yet current HCFA Medicare payment policy prohibits paying psychiatrists for multiple services provided to the same patient in the same day. Thus, physicians may well not be able to be paid for the very services that the rule requires.

6. Addressing the Current Situation:

APA believes that a number of constructive steps can be taken to deal with deaths and serious injury caused by the inappropriate use of restraint or seclusion.

First, it is absolutely vital that we have a clear understanding of precisely what is going on in the field today. While any death caused by seclusion or restraint is lamentable, we believe that the vast majority of psychiatric facilities offer safe and humane care. Although news accounts and the GAO report include disturbing data, the use of seclusion and restraint per se is not inappropriate. Rather, it appears that the problem is the inappropriate and unsafe use of these interventions in specific circumstances. Deaths and serious injuries are thus outliers we should seek to minimize and eliminate, but we must target our response to a clearly defined problem.

Second, we support mandatory uniform reporting of deaths to an appropriate state or federal authority. We suggest the appropriate authority is the Secretary of Health and Human Services, but the state licensing authority could certainly be considered. Information gleaned from such reporting will allow for a better understanding of the causes of deaths and what steps should be taken to eliminate them.

Third, we believe discussion is warranted about mandatory reporting of serious injuries. Before such reporting is required, we need to agree on a clear definition of the term "serious injury." As noted, the current JCAHO sentinel event standard offers a good starting point, but current federal legislation is fraught with problems. Above all, inappropriately loose use of terms like "psychological injury" must be avoided unless such terms are very strictly defined to mean significant injuries causing a permanent loss of function. Too loose a definition will mean that the reporting system will be swamped by reports and that the reports will lose impact.

Fourth, we strongly support staff education as a key to reducing both the overall incidence of seclusion and restraint and the possibility of death or serious injury as the result of the inappropriate use of these interventions. As we have noted, however, state of the art training does not come without costs, and it is absolutely incumbent on Congress and the Executive Branch to make certain that such costs are recoverable.

Fifth, we need to be realistic about severe mental illness. Patients in hospitals are seriously ill. They can be dangerous to themselves, to other patients, and to staff. They can be erratic, abusive, assaultive, disruptive, and combative. These are symptoms of their illness, just like elevated blood sugars are a symptom of diabetes. Physicians and staff must be able to respond to the individual demands of patients without having to be constantly second-guessed by surveyors who have little familiarity with the individual case. Staff on the front lines should not be put in jeopardy because of arbitrary standards that bear little relation to the realities of caring for patients with severe mental illness.

Sixth, we need an honest assessment of the state of the entire mental health system in the United States. As clinicians, psychiatrists in inpatient settings are seeing patients who are sicker and who have been sicker longer than ever

before. As a result of deinstitutionalization, seriously mentally ill patients are more prevalent in the community than every before. Yet these patients often lack community supports. In some states, very seriously ill patients have the right to refuse the medications that enable them to function in a community environment, thus decompensating to the point where they are dangerously out of control. It is at this stage that they are admitted to psychiatric hospitals, where we should not be surprised that they may require restraining or secluding.

Seventh, solutions should not make matters worse. Extraordinarily burdensome and costly regulatory or legislative requirements may have unintended consequences. Hospitals may refuse to admit highly agitated patients or extrude those patients who are at high risk of requiring seclusion or restraint. Rural hospitals may be unable to comply with current HCFA standards. This means that patients most in need of inpatient care may not get it, or may end up in the forensic system where their mental illness goes untreated.

Eighth, we need to avoid duplicative and overlapping responses. As noted, we are now looking at stringent new regulations from HCFA, new legislation in Congress and the states, and new JCAHO requirements. Before we pile these on top of each other, we should take the time to assess the impact of each to ensure that we are not establishing duplicative or contradictory requirements.

Ninth, Congress and HCFA must provide adequate resources to meet demands for reduced use of seclusion or restraint, new reporting requirements, and increased staffing or staff training requirements. It is completely counterproductive to set standards requiring multiple physician interventions with the same patient if HCFA won't allow payment for these interventions. Likewise, hospitals operating on tight margins must be able to recover their costs if they are required to increase staffing or staff training in response to federal rules.

Finally, neither Congress nor HCFA should try to substitute laws or rules for the independent clinical judgment of physicians. The current standards proposed by HCFA such as the 1-hour rule and some of the provisions of the various bills come perilously close to "medicine by fiat" without any guarantee that they will improve patient care. In the end, the practice of safe and effective medicine depends on the free exercise of the best clinical judgment of the physician on the scene.

Mr. Chairman, the members of the American Psychiatric Association devote their professional lives to the delivery of high quality, safe, and effective treatment to their patients. We stand ready and willing to work with you, the Executive Branch, and patient groups to ensure that we continue to meet the highest possible standards of care. Thank you.

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August 28, 1999

Nancy Ann Min DeParle
Administrator
Health Care Financing Administration
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Dear Administrator DeParle:

The American Psychiatric Association (APA) the medical specialty representing 42,000 psychiatric physicians nationwide, is pleased to make the following comments on the interim final rule that establishes a new Patients' Rights condition of participation for Medicare and Medicaid hospitals, as published in the July 2, 1999, *Federal Register* (HCFA-3018-IFC), beginning at page 36070. We will confine our comments to those portions of the rule governing the use of seclusion and restraint (proposed 482.13(e) and (f)). We also refer you to our earlier letter limited specifically to the question of timing of implementation (dated July 28, 1999), copy attached.

APA shares HCFA's concern that special care be taken when patients are placed in seclusion or restraint, particularly for psychiatric purposes. We agree that death should never be a direct result of being placed in seclusion or restraint. We concur that such interventions should be taken with the utmost care and concern for patient safety as well as the safety of staff and others, should be viewed as two of numerous alternative interventions, and should be undertaken in circumstances in which a physician determines that the patient's clinical condition warrants the intervention. Likewise, we agree that seclusion and restraint should be terminated at the earliest opportunity when the specific threat to the safety of patient, staff, or others has passed and other alternatives are clinically appropriate. We are appending to these comments a recently developed "Resource Guide on Seclusion and Restraint" that outlines general recommendations regarding the use of these interventions.

APA nevertheless has numerous concerns about the new standards. We address these below:

1. Timing and Enforcement of Rule:

We are deeply concerned that the immediate implementation of the rule has and will continue to create significant hardships for facilities. As you know, the new conditions of participation were published as an interim final rule on July 2, 1999. The rule is in force as of August 2. As we will discuss below, we believe that the rule will have a significant adverse impact on patient care standards and on hospital costs, and may require substantial changes, including the hiring of additional personnel, training of new or existing personnel, dissemination of new hospital policies, and so on. In brief, this rule is by any measure a significant departure from current practice.

It is simply not reasonable to propose a major change in clinical practice never tested in the general population and to put the standard in force on 30 days notice. The rule itself acknowledges that the provisions governing seclusion and restraint may be modified since HCFA is taking comments for an additional 30 days. Meanwhile, there are to the best of our knowledge no manual instructions, no official guidelines, no direct communications from fiscal intermediaries or HCFA regional offices to hospitals, and a host of crucial clarifications that are still required. Hospitals are, therefore, being required to make a major change on 30 days notice to comply with what is in effect a moving target.

Accordingly, we urge HCFA to acknowledge the numerous uncertainties in the rule and to postpone enforcement of the new standard governing seclusion and restraint until such time as comments have been collected and analyzed, clinical discussions have taken place, and a final rule has been issued.

2. Cost:

APA disagrees strongly with HCFA's general contention that the new standards governing the use of seclusion and restraint will be of little consequence to hospitals, physicians or other health care professionals. HCFA asserts, for example, that "we do not anticipate that they (the rules) would have a substantial economic impact on most Medicare-participating hospitals."

We widely disseminated the rule to clinicians, who overwhelmingly disagreed with this unfounded assertion. One commenter said "I believe this requirement (the requirement that patients be seen face-to-face by a physician or licensed independent practitioner within the hour) will add enormous unnecessary costs to psychiatric institutions." Another said that "to require the psychiatrist to . . . evaluate a patient who has already been evaluated by a Registered Nurse who concluded that the patient was a danger to self or others and to protect the patient from the consequences of their illness required restraint or seclusion seems redundant."

Our commenters and clinicians likewise pointed out that the proposed rule represents a substantial departure from current standards established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which does not currently require a one hour "face-to-face" physician assessment. While teaching hospitals may have physicians and/or residents on staff and on site 24 hours a day seven days a week, many other hospitals, particularly smaller hospitals, freestanding psychiatric hospitals, and rural hospitals, do not. The practical effect of the rule will be to require (assuming that were even possible in for example remote rural areas) such hospitals to have physicians on site or sufficiently in proximity to respond within the 1-hour time frame. Contrary to HCFA's assertion, this poses a significant cost to hospitals.

Likewise, we disagree strongly with HCFA's assertion that "This rule has no mandated consequential effect on State, local, or tribal governments, or the private sector and will not create an unfunded mandate." As noted above, the rule has a clear mandate on hospitals, physicians, and other health care professionals. To the extent that the rule compels Medicaid hospitals to hire additional staff, such costs may be passed on to the States as part of the hospital's cost report. To the extent that such costs are *not* recoverable, there is a clear unfunded mandate impact on hospitals, physicians, and health care professionals.

Numerous APA commenters pointed out that the 1-hour face-to-face requirement will require physicians to disrupt patient care in other settings (e.g., outpatient clinics, private practice) in order to respond to inpatient seclusion or restraint requirements set by the rule and possibly place those patients awaiting treatment in harms way. Thus, the rule will also have the effect of directly impacting care provided in other settings. This, too, is an unfunded mandate.

We believe HCFA's cost analysis and its unfunded mandate impact statement are completely unsubstantiated and inaccurate. HCFA should publish the details of the analyses that led it to conclude that there was little or no cost impact and no unfunded mandate implication. We also believe HCFA should reconsider these dubious assessments, including an extensive survey of hospitals.

For these and other reasons articulated below we specifically urge you to delay implementation and enforcement of the portion of the rule that would require, effective August 2, that patients requiring seclusion or restraint be evaluated face-to-face by "a physician or other licensed independent practitioner . . . within 1 hour after the initiation of this intervention."

3. Inappropriate Practice of Medicine:

Portions of this rule amount to little more than the attempt to specify medical practice as a Federal rule. The rule specifically defines the circumstances under which seclusion or restraint for behavioral purposes may be ordered, how long such orders may be in effect, and what standards of care must be exercised when a patient is placed in seclusion or restraints or both.

We object to the specificity of the standards on the grounds that they are an inappropriate attempt to practice medicine and are an ineffective substitute for the individual clinical judgment of the physician. Does HCFA propose to require orthopedic specialists to set fractures within an hour? Oncologists to initiate chemotherapy within an hour? Surgeons to remove an appendix within an hour? No, because HCFA recognizes that these and countless other decisions about what to do and when to do it are best made by the individual physician considering all relevant aspects of the potential medical requirements for his or her patient.

Why then should the decision about when and under what circumstances an individual patient should or should not be secluded or restrained be treated differently? We acknowledge that these interventions should be used as sparingly as possible, but it does not follow that an arbitrary and untested Federal standard, particularly as laid out in the rule, is an appropriate response.

We recommend that HCFA rethink its approach to the rules on seclusion and restraint. It would be entirely appropriate, for example, for HCFA to establish a standard that had the effect of directing hospitals to work toward an objective of significantly reducing the incidence of seclusion or restraint. Likewise it would be reasonable for HCFA to convene a consensus conference designed to encourage physicians, hospitals, and other experts to develop and field-test clinical standards of care on the use of seclusion and restraint. We stand ready to assist you in this effort.

4. 1-Hour Rule:

We do not support the requirement that a patient placed in seclusion or restraint be seen face-to-face within 1 hour by a physician or "licensed independent practitioner." While HCFA cites a standard established by administrative fiat in Pennsylvania, we note that this standard applies only to the public mental health system in the state, which -- we are advised -- is feasible because physicians are salaried staff and on site. There is not consensus and no clear evidence that a 1-hour face-to-face review is a necessary or appropriate standard.

As outlined above, the standard will increase costs and may well have the unintended consequence of jeopardizing the safety of patients and staff by forcing a precipitous decline in the use of seclusion or restraint regardless of the individual clinical needs of the patient. One commenter noted that the effect "will not improve quality of care because we do not and cannot afford to have psychiatrists on premises 24 hours a day 7 days a week; we will have to screen sicker patients out and send them to a state hospital far from home; or we will have to get a 'house doctor,' not a psychiatrist, to see patients nights and weekends (which will add nothing to their care)."

Another commenter underscored the problems with the 1-hour rule noting that "Practicing in a rural area and attending at 3 separate psychiatric units . . . it becomes an impossible task to provide 1 hour reviews of my patients placed in seclusion or

restraints. Typically I have patients in several hospitals -- what will I do when there is more than 1 patient needing my face to face review at the same time? What will my office patients do when I have to leave them waiting and drive 30 minutes to each facility?"

Our commenters overwhelmingly reject the premise that a 1-hour face-to-face physician or independent practitioner assessment of the patient is necessary. We do agree, however, that it is appropriate and desirable for the individual physician to be advised of the initiation of seclusion or restraint within the hour, and to provide oversight and approval for orders for restraint or seclusion. The best way to accomplish this objective is to retain the current practice of requiring that upon initiation of seclusion or restraint appropriately qualified and trained hospital professional staff (e.g., RN) conduct the patient assessment and communicate with the physician within the hour to obtain specific orders for continued seclusion or restraint of the patient. This communication, and the subsequent orders, should be carefully articulated in the patient's medical record.

5. Licensed Independent Practitioner:

The rule requires that face-to-face assessments be conducted by the physician or a "licensed independent practitioner." We oppose the inclusion of licensed independent practitioners. We believe that the decision to restraint or seclude a patient is a serious decision requiring a thorough understanding of the patient's medical condition, including the patient's psychiatric or other comorbid medical conditions, medications -- both psychotropic and otherwise -- that the patient is taking, and a host of other considerations. Because of the complex clinical issues, and because of the potential outcomes of restraint (and to a lesser degree, seclusion) we believe that public safety dictates that the decision to order restraints in particular as well as seclusion should come from the physician.

We understand that some few states have specifically authorized certain non-physicians to order seclusion or restraint. We believe there is a strong public purpose to be served in a higher standard for Medicare and Medicaid. We note that we have already received examples of non-physician organizations highlighting the "licensed independent practitioner" language as an opportunity for expanded scope of practice and new potential income sources. It would be completely inappropriate for this rule to be used so cynically, particularly when those seeking to use the rule to their economic benefit do not have the necessary medical training to ensure the highest standard of care.

If, after a careful legal review, HCFA determines that it cannot sustain an override of the limited state standards, we believe that the rule itself must make clear that "licensed independent practitioners" refers only to those health care professionals who are specifically authorized under current state law and under the bylaws of the hospitals where they are employed or have privileges to order seclusion or restraint. This is consistent with HCFA's explanatory statement, but we believe this must have the force of the rule, not just of the commentary.

6. Technical Issues:

a. Internal Inconsistency on Approved Use at (f)(2) and (f)(3):

We call to your attention a significant internal inconsistency in the text of the rule published on July 2. At (f)(2) the rule says "Seclusion or restraint can only be used in emergency situations if needed to ensure *the patient's* physical safety . . ." In contrast, the rule at (f)(3)(i) the rule says that seclusion or restraint must be selected "only when less restrictive measures have been found to be ineffective to protect the patient *or others* from harm." This is a significant and extremely problematic inconsistency in the permitted use of seclusion and restraint.

APA agrees that patient safety is an appropriate standard for determining whether and when to seclude or restrain a patient. However, we also strongly believe that such use must be permitted for the protection of "others" including hospital staff, other patients, and visitors. The rule as drafted is contradictory on this specific point. We also believe that staff should specifically be referenced in both instances, since they are on the front lines of patient care and most potentially at risk if a patient becomes assaultive.

b. Internal Inconsistency on Approved Use at (f)(2) and (f)(3) and (c)(2) and (c)(3):

The limitation of permitted use of seclusion or restraint to "emergency situations" to "ensure the patient's physical safety" is also problematic. The rule states at (c)(2) that the patient "has the right to receive care in a safe setting", and at (c)(3) that the patient has the right "to be free from all forms of abuse or harassment." We agree with these rights.

There is however, a conflict here with the underlying limitations on seclusion and restraint. Suppose that a patient is being highly disruptive in a manic hypersexual episode in which he is agitated and making loud, repetitive, offensive, and lewd comments to other patients and staff. Such behavior would if allowed to continue constitute a clear violation of the rights of other patients to be "free of all forms of abuse or harassment" yet to the extent that the offending patient was not in emergent threat to his own physical safety or even to the physical safety of others, the offending patient could be neither restrained nor secluded. This makes no sense.

APA believes that physicians and hospitals must have the authority to respond to patients who are highly disruptive even where the disruptive behavior does not constitute an emergency threat to the safety of the individual patient, or even to the safety of the patient "and others." In the circumstances described above, it would be entirely appropriate to seclude the disruptive patient until the episode has passed, but the standard as written would not permit this. Thus, the entire therapeutic environment is compromised, adversely affecting the care and treatment of other patients.

These inconsistencies and the general problem of regulating the practice of medicine in this regulation could be avoided if HCFA adopts our recommendation to rethink its entire approach. In the event that HCFA does not do so, we believe that the standards governing the use of seclusion and restraint must be revised.

Accordingly, we recommend that the standard be revised as follows:

"(f)(2) Seclusion or restraint should be viewed as emergency interventions to be used if needed to ensure the physical safety of the patient, staff, or others, or to prevent the disruption of the treatment environment and other less restrictive interventions have been determined to be ineffective." Existing (f)(3)(i) should be deleted, and existing (f)(3)(ii) renumbered as (i).

(c) Clarification of Application of Standards:

As you know, the rule sets separate (though similar) standards for the seclusion or restraint of patients for acute medical and surgical care (at (e)) and for behavior management (at (f)). Commenters have asked us when the standard for behavior management would apply to patients in the acute medical care setting.

For example, is a geriatric patient who has undergone hip replacement surgery and is demented following surgery subject to the medical/surgical standards or the behavior management standards? Likewise, is a patient presenting in the emergency room who appears to be in the midst of an acute mental episode but may in fact be suffering from another medical condition or adverse reaction to medications to be considered a medical/surgical or behavior management patient for purposes of seclusion or restraint?

We believe further clarification of the rule is required in this regard.

(d) Application of Standards to Residents:

The rule requires a face-to-face assessment within the hour by physicians or licensed independent practitioners. While we disagree with the both the 1-hour rule and its extension to licensed independent practitioners, we urge HCFA to clarify that "physician" includes medical residents. We believe this is implicit, but we have received several queries from hospital administrators who are uncertain that this is the case. The possibility that residents would not be covered would create substantial additional hardships for hospitals many of who rely on residents to provide off-hour coverage for precisely the purposes addressed in the rule.

7. Payment Issues:

Regardless of how it is finally implemented, we believe this rule raises profound payment issues for hospitals and physicians. Current Medicare payment policy, for example, prohibits multiple billings by the same psychiatrist for the same service for the same patient in the same day. To the extent that the rule requires psychiatrists to

conduct multiple assessments of the same patient in one day, it is imperative that HCFA clarify its payment rules to permit the psychiatrist to be paid for services rendered. To do otherwise is to completely undercut HCFA's general intention of ensuring greater patient care oversight.

Likewise, it is reasonable to expect that the rule will increase hospital costs in numerous ways. We believe it is imperative for HCFA to take immediate steps to ensure that hospitals have their cost base adjusted for payment purposes to account for their increased costs.

In a similar vein, the rule at (6) requires that "All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques . . ." We strongly concur with this requirement. At the same time, it is incumbent on HCFA to compensate individuals and facilities for the added costs of providing such training.

We would be pleased to work with HCFA and other parties to resolve these cost and reimbursement issues.

8. Conclusion:

APA commends HCFA for its efforts to ensure safe, humane, and appropriate patient care. We agree with HCFA's efforts to ensure that seclusion or restraint of psychiatric patients occurs when clinically necessary and subject to the highest standards of care. We appreciate the opportunity to comment, and welcome any opportunity for further discussions.

Sincerely,

Steven M. Mirin, M.D.
Medical Director

Enc.

RESOURCE GUIDE ON SECLUSION & RESTRAINT BY THE AMERICAN PSYCHIATRIC ASSOCIATION October, 1999

This is a statement of general principles on the use of seclusion and restraint in psychiatric treatment facilities and in psychiatric units of general hospitals. "Seclusion" is defined for this statement as "locked door seclusion." "Restraint" is defined for this statement as "physical or mechanical restraint." "Serious injury" is used as defined by JCAHO.

General Principles:

1. Our general goal is to ensure the provision of medically necessary psychiatric treatment in an environment that is safe for patients and staff.

2. Seclusion and restraint are interventions that carry a degree of risk. They may be used when, in the clinical judgement of medical staff, less restrictive interventions are inadequate or are not appropriate, and when the risks of these interventions are outweighed by the risks associated with all other alternatives.

3. Psychiatric treatment facilities and psychiatric units of general hospitals should have established procedures for the use of seclusion and restraint that conform to federal, state, or local regulations and standards of practice.

Use of Seclusion and Restraint:

4. Seclusion and Restraint may be indicated:

a. To prevent harm to the patient or other persons, including other patients, family members and staff, when other interventions are not effective or appropriate.

b. To ensure a safe treatment environment when other interventions are not effective or appropriate.

5. Use of seclusion and restraint is a matter of clinical judgement that should include a thorough understanding of the clinical needs of the individual patient and the context in which the use of seclusion or restraint is being considered.

6. Special care should be taken in assessing the clinical need for the use of seclusion and restraint in special populations. Examples of special populations are children and adolescents, the elderly, and the developmentally disabled.

Preventing the Need for Seclusion and Restraint:

7. The use of seclusion and restraint should be minimized to the extent that is consistent with safe and effective psychiatric care and the specific clinical needs of individual patients.

8. The provision of optimal psychiatric treatment, including appropriate use of psychosocial and pharmaco-therapeutic interventions, is an important component of a strategy to reduce the use of seclusion and restraint.

9. Another component of optimal psychiatric care is staff education and training. Treatment facilities must have appropriate numbers of trained staff who are familiar with the care of the specific patient population in the unit or facility.

10. Staff should be trained in the use of alternative interventions that may reduce the need for the use of seclusion and restraint.

Ordering and Implementing Seclusion and Restraint:

11. Seclusion and restraint are medical interventions that require a physician's order.

12. The physician should examine the patient and ensure appropriate monitoring and care of the patient throughout the episode.

13. Staff should be thoroughly trained and have demonstrated competence in the application of safe and effective techniques for implementing seclusion and restraint for the patient populations under their care. The techniques used should be approved by the medical staff.

14. Restraint should be applied with sufficient numbers of staff to ensure safety of the patient and staff.

15. Patients in seclusion or restraint should be carefully monitored and observed at intervals frequent enough to ensure their continued safety and the provision of humane care.

16. The decision to continue seclusion or restraint should not be viewed as "routine." Patients should be removed from seclusion or restraint when, in the physician's judgement, the patient no longer poses a threat to himself/herself, other patients, or staff.

17. The use of seclusion and restraint may be traumatic for some patients. The treatment team should consider post-intervention counseling whenever clinically indicated.

Treatment Plan Review:

18. A staff debriefing should follow each episode of seclusion or restraint. The debriefing should include an assessment of the factors leading to the use of seclusion or restraint, steps to reduce the potential future need for the seclusion or restraint of the patient, and the clinical impact of the intervention on the patient.

19. Use of seclusion and restraint, particularly when a pattern exists with an individual patient, should prompt a review of the patient's treatment plan.

20. Psychiatric treatment facilities and psychiatric units of general hospitals should engage in a continuous quality improvement process that seeks to minimize the use of seclusion and restraint consistent with good standards of clinical practice and the needs of individual patients.

Internal and External Oversight:

21. Quality assurance measures for seclusion and restraint should provide for the appropriate involvement of family members or other public parties. These measures must protect patient confidentiality and the clinical integrity of the treatment program.

22. The decision to order seclusion or restraint requires the clinical judgement of the treating physician, therefore policies governing seclusion and restraint are best dealt with through flexible and easily amendable mechanisms such as hospital policies and procedures and administrative regulations.

23. Each psychiatric treatment facility or psychiatric unit of a general hospital should have, in place, a system to review the frequency and use of seclusion and restraint by each of its clinical units or groups with the intent of sharing best practices across units and facilities.

24. Death or serious injury resulting from interventions involving seclusion and restraint should be reviewed internally. In addition to internal review, external review by or subject to an accrediting organization may also be required, with appropriate legal and confidentiality protections.

COMMUNICATIONS

STATEMENT OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

On behalf of the more than 34,000 clinically practicing physician assistants in the United States, the American Academy of Physician Assistants is pleased to submit a statement for the public record of the Senate Finance Committee's October 26, 1999 hearing on the use of seclusion and restraint in mental hospitals.

Like the witnesses who presented testimony during the hearing, the American Academy of Physician Assistants (AAPA) supports efforts to reduce inappropriate use of seclusion and restraint. Reduction of inappropriate seclusion and restraint is consistent with the physician assistant (PA) profession's support for protecting each patient's physical and emotional health and safety and the AAPA Code of Ethics, which states: "Physician assistants shall be committed to providing competent medical care, assuming as their primary responsibility the health, safety, welfare, and dignity of all humans."

The AAPA's written statement focuses exclusively on the Academy's strong objection to the use of the terminology, "licensed independent practitioner," to define which health care professionals, in addition to physicians, may order the use of seclusion or restraint and conduct a "face to face" evaluation of the need for seclusion or restraint after the initiation of the intervention. This terminology was used for the first time by the Health Care Financing Administration (HCFA) in the Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights, Interim Final Rule, published in the July 2, 1999, Federal Register. Although not contained in any of the bills introduced in the 106th Congress thus far to regulate the use of restraints and seclusion on individuals with mental illnesses, the terminology was used during the hearing. Accordingly, the American Academy of Physician Assistants is very concerned that the phrase, "licensed independent practitioner" not be used in any legislation or legislative report to define the health care professionals who are authorized to make these kinds of patient care decisions.

The terminology, "licensed independent practitioner" is particularly troublesome for physician assistants because of the word, "independent." Physician assistants are licensed health professionals who practice medicine with physician supervision. As part of the physician/PA team, PAs exercise autonomy in diagnosing and treating illnesses. PAs deliver a broad range of medical and surgical services to diverse populations in rural and urban settings. And, in almost all states, PAs can treat patients when the physician is away from the practice and can write prescriptions. PAs are not, however, "independent." Nor is independence synonymous with clinical competency or the authority under state law to provide medical care.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has used the phrase, "licensed independent practitioner" for some years, but has also made available clarifying letters and written examples for use by surveyors and others to make clear that PAs may indeed order restraint and seclusion if allowed by the hospital. Nonetheless, despite the JCAHO's attempts to provide clarifying language, the Academy knows from years of experience that the Joint Commission language is difficult to interpret and leads to varied and contradictory interpretations.

The AAPA objects to the use of the JCAHO language, particularly without clarification and as currently contained in the HCFA rule, for the following reasons—

1) Physician assistants are covered providers under the Medicare statute, authorized to provide physician medical services. Use of the term, "licensed independent practitioner" appears to apply a restriction to the current broader authority.

2) The language could be used to limit physician assistant scope of practice as defined by each state's law governing physician assistance practice. It limits the supervising physician's legal authority to delegate to qualified physician assistants this aspect of patient care.

3) Physician assistants have the educational background in medicine that prepares them to assess patients and order restraint or seclusion, if needed. Quality and patient satisfaction studies show comparable quality of care provided by physicians and physician assistants.

4) If interpreted to prohibit physician delegation of this role to physician assistants, we believe this standard would diminish the quality of care for vulnerable populations and increase costs. It would disrupt existing programs that rely on well-qualified physician assistants to provide this type of care with physician supervision as defined by state law or federal agency guideline.

"Licensed Independent Practitioner"—Problematic Language

This three-word phrase is the most problematic language we encounter in all of the JCAHO's hundreds of standards. The phrase occurs frequently in the Joint Commission standards (not only in the restraint and seclusion section (and results in widely varied and unpredictable interpretations by both hospitals and individual Joint Commission surveyors. The American Academy of Physician Assistants is dismayed that it has suddenly appeared in the Medicare and Medicaid Conditions of Participation (COPs).

This terminology is bad public policy. It fails to reflect today's health care delivery system of inter-disciplinary team practices. This policy language results in inappropriate limiting of physician assistant state-authorized scopes of practice and erects unintended obstacles to effective utilization of physician assistants. This language causes never-ending confusion for physician-PA teams and the credentialling staffs in hospitals. It causes needless confusion and frustration during Joint Commission surveys.

Physician Assistants—Clinical Preparation

Physician assistants practice medicine under the delegated authority and supervision of licensed physicians. They are qualified by graduation from an accredited physician assistant educational program and/or certification by the National Commission on Certification of Physician Assistants.

Physician assistant programs are accredited by the independent Commission on Accreditation of Allied Health Education Programs, whose review committee on PA education is composed of representatives from the American Medical Association, the American Academy of Family Physicians, the American College of Surgeons, the American Academy of Pediatrics, the American College of Physicians-American Society of Internal Medicine, the Association of Physician Assistant Programs and the American Academy of Physician Assistants.

The PA curriculum parallels that of medical school. Approximately two years of science pre-requisites are followed by a year of didactic coursework and a year of clinical rotations through the major medical and surgical specialties. The AAPA would be pleased to provide more detailed information about PA education, if it would be helpful.

Upon graduation, PAs sit for the Physician Assistant National Certifying Exam. The exam is developed by the National Board of Medical Examiners and administered by the independent National Commission on Certification of Physician Assistants. The Commission is composed of representatives from the American Medical Association, the National Medical Association, the American Academy of Family Physicians, the American College of Physicians-American Society of Internal Medicine, the American College of Surgeons, the American Academy of Pediatrics, the American Hospital Association, the US Department of Defense, the Association of American Medical Colleges, the Federation of State Medical Boards, the Association of Physician Assistant Programs and the American Academy of Physician Assistants. To maintain current certification, PAs must complete 100 hours of CME every two years and take a recertification exam every six years.

Scope of Practice and Licensure

What was HCFA's intent in choosing the phrase "physician or other licensed independent practitioner?" Was the intent to allow the assessment of patients and the appropriate ordering of restraint or seclusion by practitioners who are permitted by state scope of practice do so? If narrowly interpreted (which we believe is likely (this interim final rule would prohibit PAs from practicing to the extent allowed by most state laws.

Physician assistants are licensed practitioners who provide medical care with physician supervision. They are not "independent practitioners." In all states that regulate physician assistants (that is, all states except Mississippi), physicians may delegate to PAs those medical duties that are within the physician's scope of practice, the PA's training and experience, and the PA's scope of practice under state law. Laws governing supervision are flexible. Except in very specific circumstances,

states allow PAs to deliver care without the physical presence of the supervising physician, as long as the physician is available for consultation by telecommunication. The legal scope of practice for some federally employed PAs is defined in federal agency guidelines rather than state law.

Within the physician-PA relationship, PAs exercise autonomy in medical decision making and provide a broad range of diagnostic and therapeutic services. Their duties typically include performing physical examinations, diagnosing and treating illnesses, ordering and interpreting lab tests, assisting in surgery, and making rounds in nursing homes and hospitals. In 46 states plus the District of Columbia and Guam, physicians may delegate prescriptive authority to the PAs they supervise.

State PA laws do not prohibit physicians from delegating to physician assistants patient assessment and ordering of restraint or seclusion. The following are a few examples provided to illustrate how some state laws define the PA scope of practice and its relationship to the supervising physician's delegatory authority.

New York regulations require that medical acts, duties, and responsibilities performed by a PA must be assigned by a physician, within the scope of the physician's practice, and appropriate to the education, training and experience of the PA. (New York Code Rules and Regulations, Title 8, Chapter II, Subchapter A&B, Parts 59 and 60, Title 10 (Health) Subchapter M, Part 94.2)

North Carolina regulations state that the PA performs medical acts, tasks, or functions with physician supervision. PAs perform those duties and responsibilities that are delegated by their supervising physician. (21 NCAC Subchapter 320.0008—Physician Assistant Regulations)

Texas regulations state that the PA may provide medical services within the education, training and experience of the PA that are delegated by the supervising physician. The services may be performed in any place authorized by the supervising physician, including but not limited to the clinic, hospital, ambulatory surgical center, patient home, nursing home, or other institutional settings. Services may include but are not limited to histories and physicals, ordering or performing diagnostic and therapeutic procedures, formulating a working diagnosis, developing and implementing a treatment plan, monitoring effectiveness of therapeutic interventions, assisting at surgery, patient counseling and education, and referrals. (Texas Rules for Physician Assistants, Chapter 185.11)

Washington state regulations define the functions of the PA to include performing diagnostic, therapeutic, preventive and health maintenance services in any setting in which the physician renders care in order to allow more effective and focused application of the physician's particular knowledge and skills. (WAC 308–52–149)

Physician Assistant Quality of Care

The American Academy of Physician Assistants is unaware of any studies that specifically evaluate the ordering of restraints by physician assistants. However, there have been numerous studies that have examined the overall quality of care PAs provide. All have found the quality of care provided by PAs to be similar to that provided by physicians.

A widely quoted 1986 study by the Congressional Office of Technology Assessment found the quality of care provided by PAs to be equivalent to that of physicians, within the limits of the PAs' expertise. The report also discussed the medical staffing shortages faced by nursing homes and suggested that "PAs are uniquely suited to provide the types of care needed by nursing home residents with chronic conditions and their associated disabilities." OTA investigators found increased quality of care and decreased emergency room visits and hospitalizations of nursing home patients when group practices that included PAs provided nursing home care. That 1986 OTA report advocated for changes in Medicare and Medicaid regulations that were limiting the role of NPs and PAs in nursing homes. (Technology Case Study 37: Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis. Congress of the United States Office of Technology Assessment. Washington, DC, December 1986.)

A 1994 federal study of state practice environments reported, "Within their areas of competency, and with appropriate training and supervision, these practitioners may provide medical care similar in quality to that of physicians and at less cost." (Seksenski ES et al. State Practice Environments and the Supply of Physician Assistants, Nurse Practitioners and Certified Nurse-Midwives. New England Journal of Medicine, Nov. 10, 1994; Vol.331:1266–1271.)

A recent study by Ackermann and Kemle showed a dramatic and sustained reduction in acute care hospitalization and reduced cost to the Medicare program by the utilization of a physician assistant in caring for the geriatric population in a long term care facility. (Ackermann RJ and Kemle KA. The Effect of a Physician Assist-

ant on the Hospitalization of Nursing Home Residents. Journal of the American Geriatrics Society. May 1988; Vol 46:610–614.)

Physician Assistants as Medicare Covered Providers

Long-standing Medicare statutes, augmented by provisions contained in the Balanced Budget Act of 1997, make it clear that PAs are authorized to provide physician medical services to Medicare patients. Within that context, the medical services provided by the physician assistant must be (1) within the PA's legal scope of practice; (2) delegated to the PA by the PA's supervising physician; (3) medically necessary; and (4) covered by the Medicare program.

Caring for the Underserved

Since the release of HCFA's interim final rule, the Academy has received calls from institutions where physician assistants practice. Administrators are alarmed and uncertain about what this language means for their utilization of PAs. PAs are concerned that their ability to provide the most appropriate care for vulnerable elderly and mentally ill patients will be undermined. The following are just two examples.

The AAPA heard from a psychiatric hospital in rural Maine, where for 15 years physician assistants have provided overnight in-house coverage with a psychiatrist on call for consultation. The PAs are qualified and legally authorized to assess patients, order restraints or seclusion if necessary, and provide ongoing reassessments of the patient. The PA on duty assesses the patient within minutes of implementing the restraint or seclusion, rather than waiting much longer for the arrival of the on-call psychiatrist. The on-call psychiatrist is available by telephone for consultation with the PA and can come to the facility, if necessary. Not only does HCFA's regulatory language threaten to disrupt a program that has worked beautifully for years, the administrators are worried about the impact this could have on their already difficult task of recruiting psychiatrists.

The Academy also heard from a community hospital in the Baltimore area where restraint use has dropped by 50 percent since the hospital began utilizing PA house staff to assess patients when unit staff request restraint or seclusion. Rather than unit staff phoning the attending physician for a verbal order, the in-house PA provides a face-to-face assessment before making a decision about ordering restraint or seclusion.

Alternative Language

Selecting alternative language that would allow full and appropriate utilization of supervised professionals would support HCFA's stated goal of "working in partnership with the rest of the health care community to institute better, more commonsense ways of operating" and HCFA's stated commitment "to working with affected parties to implement revised COPs that impose the minimum burden on hospitals and allow hospitals maximum flexibility in meeting Federal requirements necessary to fulfill our quality of care responsibilities." (Federal Register, December 19, 1997, pages 66726–7.)

The American Academy of Physician Assistants recommends that ". . . physician or other licensed, certified or registered professional practicing with the delegated authority and supervision of a doctor of medicine or osteopathy," be used as an alternative to "licensed independent practitioner." The use of the alternative language would not adversely affect the quality of patient care. Supervised practitioners who ordered restraints or seclusion would do so within the context of their supervised practice. Physician assistants with appropriate education and expertise to order seclusion or restraint could only issue the order and assess the patient if they were granted authority by the state (or federal agency) through their legal scope of practice, by agreement of the supervising physician, and by policies of the hospital.

The proposed alternative wording would support an intention of limiting the ordering of seclusion and restraint and would avoid inappropriately limiting the scopes of practice of thousands of direct patient caregivers who provide a large portion of the care in the facilities that would be most impacted by this regulation. At the same time, it would also keep the authority for the care of the patient with the physician, who could by state law or federal agency regulation appropriately delegate the ordering and the subsequent face-to-face assessments to a qualified physician assistant or other qualified practitioner. This would allow flexibility for many of the smaller and rural institutions most affected by these rules.

Conclusion

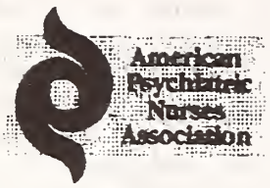
By and large, many of the patients who end up in seclusion or restraint are members of vulnerable, underserved populations such as the mentally ill and the elderly.

When a patient requires restraint or seclusion it is usually a situation of high distress (for the patient, their family and the caregivers. The ability to recruit staff to care for patients in these populations and in public institutions that serve many of them is very constrained. Many physicians and institutions have improved their ability to address the needs of these underserved populations by adding physician assistants to their practice teams. Maximizing resources should be the goal, not eliminating an entire classification of practitioners who are recognized providers under Medicare law and who have a 30-year track record of providing quality care in teams with physicians.

The AAPA is particularly concerned that this terminology, "licensed independent practitioner," has appeared in the COPs, which apply primarily to small rural institutions. The physician assistant profession has long been a stalwart in the delivery of care to rural Americans. Almost a third of the nation's 34,000 practicing PAs (10,400 PAs) provide care in communities of under 50,000 people. Of those rural PAs, 2,500 practice in communities of 10,000–25,000 residents, 2,000 work in communities of 5,000–10,000 residents, and 2,800 provide care in communities of fewer than 5,000 residents.

The Academy cannot overstate how problematic this "licensed independent practitioner" language has been in Joint Commission standards. Accreditation standards must allow for state scopes of practice, physician delegation as leaders of patient care teams, and flexibility in meeting patient needs.

The American Academy of Physician Assistants stands ready to assist you in any way we can to improve the care and safeguard the lives of patients.



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October 25, 1999

The Honorable William V. Roth, Jr., Chairman
Senate Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

On behalf of the American Psychiatric Nurses Association (APNA), I would like to commend you for initiating a hearing to discuss the use of seclusion and restraint in institutions for mental disabilities. APNA appreciates your leadership on this important issue. The APNA, with a membership of approximately 4,500, provides leadership to advance psychiatric-mental health nursing practice, improves mental health care for culturally diverse individuals, families, groups and communities and shapes health policy for the delivery of mental health services.

APNA would like to request that legislation regarding the use of seclusion and restraint include provisions authored by Senator Lieberman that seek to establish and ensure much needed patient protections. In particular, APNA supports Senator Lieberman's proposal that would allow licensed independent practitioners to order seclusion or restraint. Further, APNA applauds the Senator for recognizing that seclusion or restraint should only be used "to ensure the physical safety of the individual or other individuals in the care or custody of the provider, staff member or others." APNA firmly believes that legislation is needed in order to ensure that seclusion or restraint is never used for purposes related to discipline or convenience and applied in emergency situations only. Again, Senator Lieberman is to be commended for his leadership on this issue.

As the process moves forward, however, APNA would like to suggest the addition of provisions that would help strengthen Senator Lieberman's proposal. To begin, APNA hopes that federal guidelines related to the use of seclusion and restraint can be extended to cover all patients -- in all settings. Secondly, while we applaud the Senator's efforts to begin to divulge information regarding improper use of seclusion and restraint, APNA believes more detailed data reporting requirements should be established. Specifically, APNA would urge the recording and assessment of data containing (1) the number of incidents of seclusion, (2) the number of incidents of restraint, (3) the number of patients in seclusion, (4) the number of patients in restraint and (5) the average number of hours by incident, and by patient, in both seclusion and in restraint. This type of data would help the "benchmarking" process and assist health care professionals in their quest to provide the best patient care possible. Finally, APNA would encourage the inclusion of

language pertaining to staff training. There is an urgent need to ensure that health professionals receive ongoing training on behavioral techniques to help avoid the use of seclusion or restraint and stress the safety of the patient and the providers of care.

We are hopeful that these and other considerations will be discussed during your hearing and subsequent meetings. As you know, the improper use of seclusion and restraint is an issue that requires our immediate attention. Due to the unique perspective APNA members offer, we have recently announced the formation of a Task Force on Seclusion and Restraint. One important goal of the Task Force will be to develop professional standards on this issue. Further, members of this body will represent the geographical and practice diversity of APNA. Task Force members include nurses who work in practice settings (such as public, private, academia); with different patient populations (such as adult, child/adolescent, geriatric), and who have specific roles (such as clinical nurse specialist, staff nurse, nurse practitioner, nurse manager). We are excited about the Task Force and will continue to provide you with information as developments occur.

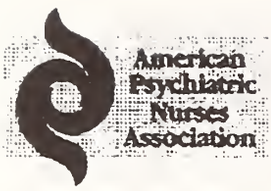
Again, thank you for holding a hearing on the use of seclusion and restraint. APNA appreciates your dedication and looks forward to working with you during the remainder of the 106th Congress and beyond. Should you have any questions or require additional information, please do not hesitate to contact me or have your staff contact Rob Morrison of APNA Government Relations at (202) 857-5322.

Sincerely,

Jane Ryan

Jane Ryan, RN, MN, CNAA
President

Cc: The Honorable Daniel P. Moynihan, Ranking Member
Tim Gordon, Executive Director



1200 19th Street, NW
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American Psychiatric Nurses Association (APNA)
Rationales for Components of Restraint and Seclusion
Approved by APNA Board of Directions, 8/22/99

Issue/Component	APNA Required	Rationale
Development of professional standards	APNA Task Force developing standards in collaboration with other professional organizations	Any future legislation on seclusion and restraint requires the development of professional standards which would provide the framework for quality care for those behaviors of any person which constitute a risk for safety for themselves or others.
Populations Covered	All patients in all settings, all reimbursements	The entrance to most hospitalizations is through emergency departments and in some cases the correctional system. Persons presenting with aggressive, violent, hostile behaviors are most likely to be treated in emergency departments, in fact most patients need medical clearance before admission to hospitals or special treatment settings. Patients may also exhibit these same behaviors in any care setting thus it is important to apply the same standards of care across all settings
Guidelines for Restraint/ Seclusion	The use of seclusion/restraints are only for emergency interventions to provide the least restrictive environment to maintain safety for patients and staff.	The guidelines are necessary to insure that patients are cared for in the least restrictive environment and that requirements for use are met in a safe, respectful manner from initiation to termination of seclusion and/or restraint. Staff safety must also be maintained and staff should be trained in seclusion and restraint procedures.
Federal reporting of restraint/ seclusion	Annually Utilize systems in place Report to include number of incidents of	Reporting of all incidents is necessary for accurate tracking of potential abuses of these modalities. Reporting should include not only the number of

Issue/Component	APNA Required	Rationale
	seclusion/restraints; average number; average hrs/patient and duration of each	occurrences, but also the length of time of each occurrence. The time of day and which shifts use seclusion and restraints the most should also be monitored. The reporting should be anonymous in terms of patient name but give specific demographic information (age, gender, admission, date, ethnic background, and diagnosis). Restraint reporting would also led to "best practices" facilities who report no use and truly have a policy against the use of seclusion and restraint. These facilities as well as those that significantly reduce the use of seclusion and restraints should be recognized and asked to mentor other facilities.
Federal reporting of deaths	Report deaths and sentinel events	Absolutely any death occurring must be reported and should be investigated by state and/or federal agencies regardless of pay source of the facility and appropriate sanctions taken against the facility.
Training of restraint and seclusion use and alternatives; crisis intervention	Initial (orientation) Annual training (re-certification)	Staff should be trained initially in the correct procedures to follow when using seclusion or restraints. They should also be made aware of the alternatives, and the importance of using seclusion and restraints only as an emergency short term measure when a patient is dangerous to himself or others and cannot be redirected by any other means.
Staffing	Require utilization of staffing regulations and guidelines ensuring adequate registered nurse staffing	Adequate levels of staff trained in the use of seclusion and restraints are necessary to monitor the patients during the period they are secluded or restrained. Patients have hurt themselves trying to get out of restraints and while secluded, so timely and frequent assessment by sufficient staff and RNs is necessary. Without adequate staff, seclusion and/or restraints may be implemented after they are no longer

Issue/Component	APNA Required	Rationale
		necessary. When seclusion and restraints are discontinued, close monitoring is again needed to reintegrate them back into the environment.
Sanctions	Sever program participation Reports to appropriate professional licensing boards	Sanctions are necessary both to deter excessive use of seclusion and/or restraints and to penalize those facilities that fail to adequately protect their staff and their patients.

American Psychiatric Nurses Association

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August 27, 1999

Ms. Nancy-Ann Min DeParle, Administrator
Health Care Financing Administration (HCFA)
Department of Health and Human Services
Room 443-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: File Code HCFA-3018-IFC (64 Federal Register 36070), July 2, 1999

Dear Ms. DeParle:

On behalf of the American Psychiatric Nurses Association (APNA), I am submitting these comments in reference to the interim final rule concerning the use of restraint and seclusion in the Patients' Rights Conditions of Participation (COPs) (42 CFR Part 482) for hospitals receiving Medicaid and Medicare payments. This interim final rule was published in the *Federal Register* on July 2, 1999. The APNA, with a membership of approximately 4,500, provides leadership to advance psychiatric-mental health nursing practice, to improve mental health care for individuals, families, groups and communities, and to shape health policy for the delivery of mental health services. There is no doubt that APNA members have a unique perspective regarding the use of restraints and seclusion. As a result, we are confident that patients in facilities across the U.S. will benefit from the modifications suggested by the comments listed below.

Overall, APNA would like to commend the Health Care Financing Administration (HCFA) for its work regarding restraint and seclusion guidelines. The proposed interim final rule provides much needed guidance for the use of restraint and seclusion in the behavior management arena while carefully creating more flexibility in the acute medical and surgical areas. The definitions included by HCFA also recognize the need to view the use of restraint and seclusion as actions that are "situation specific." While HCFA has made great strides, APNA would like to offer the following comments to strengthen regarding the interim final rule.

Intent to Examine Restraint and Seclusion in Other Settings
Section C (Page 36071)
HCFA wrote: "We are requesting comment on whether we should set forth the same requirements as promulgated in this rule or whether more stringent standards would be appropriate. For example, is the current standard for continual monitoring of patients in

restraint adequate for children or should all restraints for children be monitored by direct staff observation?"

APNA Response: APNA believes that the strict, prescriptive standards being put forth in this document for seclusion and restraint in behavior management should be extended to all health care entities having provider agreements with HCFA (where psychiatric patients are housed and are secluded or restrained). This should include inpatient psychiatric services for individuals under 21 years of age as well. However, APNA believes there are certain considerations that must be made when treating certain populations. For example, in using restraints and seclusion with children, different standards should apply. Below, APNA offers specific comments on guidelines governing restraints and seclusion time frames. Again, the "secluded or restrained patient" in any setting, but especially in a psychiatric setting, is the "most vulnerable" patient APNA members care for. These patients need the most stringent yet appropriate standards of care to ensure proper protection. These patients, along with suicidal patients and those receiving ECT, are often viewed as the "highest risk" patients in psychiatry.

Section D: Conformance of Patients' Rights in Hospitals with the Consumer Bill of Rights and Responsibilities (CBRR) (Page 36071)
HCFA wrote: "We ...ask for comment on the following additional consumer rights, which we believe would need to be incorporated in the COPs in order to achieve compliance with the Bill of Rights..." (A list of additional consumer rights were then identified.)

APNA Response: APNA would like to express its support for each of these additions as listed.

Advanced Directives (Page 36075)
HCFA wrote: We proposed that the patient has the right to formulate Advance Directives and to Have Hospital Staff and Practitioners Who Provide Care in the Hospital Comply With These Directives.

APNA Response: APNA applauds the important additions around Advanced Directives as they relate to psychiatric emergencies. The membership supports the efforts to clarify the integration of patient respect, dignity, and comfort as components of an emotionally safe environment. Adding this to the interpretive guidelines that are given to HCFA surveyors represents movement forward on this issue. It also seems clear that very important and significant information is and will be contained in these interpretive guidelines. APNA believes that psychiatric nurses and their patients would profoundly benefit from the information included in the interpretive guidelines. As a result, APNA believes HCFA must work with APNA and other stakeholders to effectively communicate information contained in these guidelines to psychiatric nurses and others who need to have that knowledge.

Seclusion and Restraint
Acute-level Medical & Surgical Care versus Managed Behavior Care (Page 36078)
HCFA wrote: *"In the final rule, we have attempted to differentiate between situations where a restraint is being used to provide acute-level medical and surgical care and those where restraint or seclusion is used to manage behavior."*

APNA Response: APNA believes that the separation of the restraint and seclusion standards into behavior management and acute medical and surgical settings is to be applauded. These settings do indeed require different yet appropriately sensitive standards.

Time-limited Orders (Page 36079)
HCFA wrote: *"Accordingly, we are accepting commenters' suggestions to regulate the time frames within which certain actions must occur in the behavior management scenario."*

APNA Response: APNA is supportive of the concept of time-limited orders. In particular, APNA is supportive of the use of JCAHO's 1999 Hospital Accreditation Standards, which limit written orders for restraint or seclusion to "4 hours for adults, 2 hours for children and adolescents ages 9 to 17, or 1 hour for patients under age 9."

Consultation of the "Treating" Physician (Page 36079)
HCFA wrote: *"[w]e are requiring that if the restraint or seclusion order is written by a physician or licensed independent practitioner other than the "treating" physician, the treating physician must be consulted as soon as possible."*

APNA Response: This section describes the qualifications of those who are able to write orders for seclusion and restraint. Professionals who can function independently within the scope of their licenses must satisfy the requirements set forth by law, individual hospitals and the responsibilities that accompany specific clinical privileges. APNA believes those APRNs who have hospital privileges to admit and/or treat should also have the ability to write an order for seclusion and restraint. HCFA also states that the "treating" physician must be consulted as soon as possible when an order for seclusion or restraint is written by another physician or licensed independent practitioner. If the APRN has full hospital privileges to admit, treat and discharge patients, there will be certain instances where there is no treating physician to consult. We are aware that Medicare patients, by law, must remain under the care of a physician. However, APNA believes qualified psychiatric nurses should play an increased role in the ordering of restraint and seclusion process because of the clearly identified problem of having an accessible physician who is properly trained and versed in the use of restraints and seclusion.

Immediate Need for Assessment (Page 36079)
HCFA wrote: *"In situations where a restraint must be used for behavior management, increased vigilance is required because of the heightened potential for harm or injury as the patient struggles or resists. There is an immediate need for assessment of what has triggered this behavior and for continuous monitoring of the patient's condition. To address the need for quick assessment of the condition, we are specifying that the physician or licensed independent practitioner see the patient face-to-face within 1 hour of the application of the restraint or the use of seclusion."*

APNA Response: APNA agrees that patients requiring a restraint also require and deserve timely assessment of their condition. APNA certainly appreciates the role physicians play in the management of psychiatric patients. APNA also supports allowing restraint orders to be written by those who meet state and hospital requirements, and are trained in prevention and management of physically aggressive patients.

Use of Seclusion and Restraint Simultaneously (Page 36080)
HCFA wrote: *"We are strengthening the final rule by specifying that physical restraints may not be used in combination with seclusion unless the patient is either (1) continually monitored face-to-face by an assigned staff member; or (2) is continually monitored by staff using both video and audio equipment. "*

APNA Response: APNA does not envision the need to ever combine the use of seclusion with restraint. Here, APNA is using the more traditional sense of the word "seclusion." (i.e. where a patient is secured in a seclusion room). In this case, APNA agrees with other national advocacy organizations, including the Bazelon Center for Mental Health Law, in opposing the simultaneous use of both seclusion and restraint. HCFA offered the definition of seclusion as "the involuntary confinement of a person in a room or an area where the patient is physically prevented from leaving." APNA believes that a patient who is locked in restraints is also more than theoretically in isolation (according to the HCFA definition) because the patient is physically prevented from any movement, especially leaving the immediate area. APNA believes that a patient should never be both locked in restraints and then placed in a locked seclusion room: this is so even if a staff member is also in that room on a monitoring basis.

APNA notes that the interim rule fails to offer a concrete definition of "continually monitored." Instead, HCFA plans to provide a definition of "continually monitored" though interpretive guidance. APNA wishes to express concerns to HCFA regarding the use of video monitoring while patients are in behavioral restraints. Video monitoring may have the effect of discouraging direct human contact with patients in behavioral restraints despite the vulnerable state of these patients.

Staff Training (Page 36078)
HCFA wrote: *"[w]e have added language to the final rule that will require a training program on restraint for staff. We have also noted that these training programs should review alternatives to restraint and seclusion, to teach skills so that staff who have direct*

patient contact are well equipped to handle behaviors and symptoms as much as possible without the use of restraints or seclusion."

APNA Response: APNA agrees that staff ought to be taught skills to ensure their ability to properly handle behaviors and symptoms as much as possible without the use of restraints or seclusion. APNA believes other important training considerations must be added to the interpretive guidelines. This includes the need for staff to experience training in values clarification, cultural diversity, and countertransference. It is commonly acknowledged that patients become more agitated and lose control when staff respond in a manner that provokes the patient. It seems clear that staff may respond in a non-therapeutic manner due to the inability to emotionally connect with patients. In addition, staff may have a different set of values than the patient, which may also stimulate patient unrest. Staff often respond to situations by instinctively relying on their own frame of reference (i.e. their own cultural background). This miscommunication can provoke certain patients. Nonetheless, APNA wishes to emphasize that training is needed to help staff gain an understanding of his/her own self, and for staff to subsequently examine how his/her own behavior can influence the patient's behavior - and vice versa.

APNA also would welcome the opportunity to work with HCFA and other interested parties to develop professional standards for training which would provide the framework for measuring the quality of care given to any person whose behaviors constitute a safety risk for themselves or others.

Data Reporting Requirements (Page 36081)
HCFA wrote: "[w]e are soliciting comment on the pros and cons of requiring the reporting of serious injury or abuse related to the use of restraints or seclusion, as well as the type of injury or abuse that would be reported, and the process whereby these incidents would be reported."

APNA Response: APNA would like to see the reporting requirement expanded beyond the reporting of deaths related to seclusion or restraint. APNA believes hospitals, state mental health authorities, and federal officials should coordinate the recording of data containing (1) the number of incidents of seclusion, (2) the number of incidents of restraint, (3) the number of patients in seclusion, (4) the number of patients in restraint and (5) the average number of hours by incident, and by patient, in both seclusion and in restraint. Currently, each hospital already maintains this type of data. Therefore, costs associated with recording and categorizing this type of important data should remain relatively low. Because this data is not currently available in a coherent and consistent manner on the state or federal level, benchmarking has not been possible. The recording of the aforementioned data would also permit a system whereby hospitals with best practices can be identified. Similarly, the proposed reporting standards would also help to identify those facilities having poor records associated with restraint and seclusion. Those hospitals with poor practices would be identified as those having an inordinately high number of hours of seclusion or restraint; thus relying on seclusion and restraint as a primary intervention rather than utilizing other interventions that emphasize prevention.

APNA encourages timely reporting of deaths associated with restraint and seclusion (i.e. within a specified, quantifiable time frame) and the reporting of "sentinel events." Sentinel events can be defined as any unexpected occurrence involving a substantial impairment of the physical or psychological condition of a resident or patient, including significant burns, lacerations, abrasions of the skin, bone fractures, substantial hematoma, internal injuries, or injuries that occur as a result of repeated harm to any bodily function or organ.

APNA also recommends that certain portions of the data be reported in an anonymous fashion. For example, the patients' names should be omitted. However, other specific demographic information should be included. This includes age, gender, admission date, ethnic background, diagnosis, etc. Among other things, this type of information can help identify certain trends taking place in facilities across the country.

Physician-only Orders (Page 36082)
HCFA wrote: "[w]e are interested in receiving comments on whether we should adopt more restrictive requirements that would allow only physicians to order restraints or seclusion for behavior management."

APNA Response: APNA is opposed to adding a requirement that would allow only physicians to order restraints or seclusion for behavior management. As mentioned above, APNA obviously appreciates the role physicians play in the management of psychiatric patients. However, APNA also supports allowing restraint orders to be written by those who meet state and hospital requirements, and are trained in prevention and management of physically aggressive patients. It must be mentioned, however, that if HCFA were to add the "educational requirement" to physicians, very few would be able to immediately write orders for seclusion and restraint. It is not unusual for physicians to lack training in seclusion and restraint practices.

It must be restated that APNA supports timely assessment of patients who have been in restraints or in seclusion. As HCFA mentioned, some in the mental health community have requested that physicians be the only professionals allowed to not only order the restraints or seclusion, but also to be the only professional able enough to assess these patients within one hour of an episode. APNA disagrees with this view.

We do appreciate the fact that many facilities, especially those in rural settings, do not have adequate access to physicians. This is indeed the case in many instances. However, APNA believes an alternative system could be created whereby facilities could either hire an APRN or enter into a contract with an independent APRN in order to ensure that a qualified (determined by law and hospital policies) professional can be available for patient assessments. As we all know, patients warrant the attention of physicians in a medical emergency in a variety of circumstances. Similarly, psychiatric patients in a psychiatric emergency require the same type of specialized, targeted and appropriate treatment.

In conclusion, APNA wishes to recognize HCFA's work in developing these standards regarding restraints and seclusion. Similarly, APNA acknowledges that much work remains. However, our patients require and deserve our best efforts. These comments reflect our continued goal of providing patients with the best care possible. Implementing our recommendations, along with the APNA-supported proposals already contained within the interim final rule, will require hard work, cooperation and communication. We understand many challenges remain. As a result, APNA looks forward to working with the Administration, Congress, patients and their families along with other members of the health care community as we move forward.

APNA appreciates the opportunity to provide these comments. In addition, please find the enclosed chart for your convenience. Should you have any questions or require additional information, please do not hesitate to contact me at (202) 857-5322.

Sincerely,

Jane Ryan

Jane Ryan, RN, MN, CNAA
President

Cc: Timothy Gordon, Executive Director
APNA Board Members
APNA Government Relations Committee

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CHILDREN AND ADULTS WITH MENTAL RETARDATION ARE VULNERABLE TO ABUSE AND NEED STRONG PROTECTIONS

The Arc of the United States strongly supports all efforts to end abuse and the misuse of restraints, and seclusion

For Immediate Release
Tuesday, Oct. 26, 1999

Contact: Dr. Kathleen McGinley
202-785-3388

Washington, D.C. — The Arc of the United States, a national organization on mental retardation, celebrated 50 years of advocacy on behalf of children and adults with mental retardation and their families at its annual convention this past weekend. One overarching effort of The Arc during these 50 years has been to ensure that people with mental retardation are seen as valued members of the community – members whose personal and civil rights are respected and protected. After years of discrimination, positive changes have taken place over the last several decades. The rights of people with mental retardation to live, learn, work, and be part of their communities have been strengthened by the passage of Section 504 of the Rehabilitation Act, the Individuals with Disabilities Education Act, the Fair Housing Amendments Act, the Civil Rights for Institutionalized Persons Act, and the Americans with Disabilities Act.

Unfortunately, the current scene is not all rosy. Too often, we find that general attitudes towards people with mental retardation have not changed. They are still seen as "different" and these perceived differences evoke a range of emotions from misunderstanding and apprehension to feelings of superiority and hatred. The anti-disability bias that stems from these feelings takes many forms, including the misuse of aversive behavioral techniques, such as restraints and seclusion, to try and "control" people's behavior.

The Arc of the United States endorsed the use of positive behavioral supports that preclude the use of restraints and seclusion except in an extreme emergency. Individuals who provide supports and services to people with mental retardation and other disabilities must be required to receive training in the use of positive behavioral supports not in the "better use" of restraints. In fact, last week, The Arc awarded its 1999 Distinguished Research Award Dr. Edward Carr, State University of New York at Stony Brook. Dr. Carr was honored for the work he has done in the area of positive behavioral supports.

50 Years
The Arc
Service · Advocacy · Quality · Leadership

a national organization on mental retardation
formerly Association for Retarded Citizens of the United States

The Arc of the United States also supports holding entities responsible for any abuse, injuries or deaths that may result because of the use of aversive methods of behavior control, such as restraints and seclusion, especially entities that receive federal funds through programs like Medicaid or Medicare. The Arc is extremely pleased that the misuse of restraints and seclusion has become an issue with both the Congress and the Administration. The hearing held today before the Senate Finance Committee is just one more step in the right direction. The Arc endorses the following recent efforts.

- House and Senate legislative initiatives (Reps. DeGettte (D-Col.) and Stark (D-Calif.) and Sens. Lieberman and Dodd (D-Conn.)) have been introduced to protect people with mental disabilities, including people with mental retardation and other developmental disabilities. The Arc urges continued action on these important bills.
- Sens. Specter (R-Pa.) and Harkin (D-Iowa), Chair and Ranking Member of the Senate L-HHS-ED Appropriations Subcommittee, shone a spotlight on this issue at an April hearing. The Arc supports their continued commitment to this issue as shown in their FY2000 funding decisions.
- The Government Accounting Office (GAO) recently released a study, *Improper Restraint or Seclusion Use Places People at Risk*, that recognizes that people with serious mental illness or mental retardation are among the country's most vulnerable citizens. The Arc supports its recommendations that protections must be in place in all settings, including the community.
- The Health Care Financing Administration (HCFA) has been proactive on this issue, publishing proposed Hospital Conditions of Participation related to the misuse of restraints and seclusion.

The Arc urges Members of Congress and the Administration, as well as providers of supports and services for people with disabilities to see people with mental retardation as people – deserving of respect and safety. Too often they are victimized. This can be seen in the attached articles from the *Wilmington Delaware News Journal* on the 1993 death – due to restraints -- of a young woman with mental retardation. This can also be seen in a Feb. 27, 1999 *New York Times* article on a two-year investigation at Polk Center, Pennsylvania's largest state institution for people with mental retardation, an investigation that led to six doctors being charged with various crimes. Two were charged in the deaths of three people and charges of assault and neglect were filed against four others, accused of using sutures and surgical staples to close wounds without giving the people anesthesia.

The Arc is the nation's largest volunteer organization solely devoted to improving the lives of all children and adults with mental retardation and their families. Today there are over 100,000 members within approximately 1,000 state and local chapters nationwide.

The News Journal
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SATURDAY Sept 25, 1993

Patient's death blamed on restraint

By CHRIS DOMANUE
Staff reporter

The state medical examiner's office said Friday a 31-year-old Stockley Center patient died Sept. 6 as a result of being restrained.

The report said Mardee Cumpler died of "acute respiratory and cardiac arrest caused by positional pressure on the upper body during restraining."

Cumpler, who lived at the state's center for the mentally retarded in Georgetown since 1973, had severe retardation and was diagnosed as low functioning with violent behavior.

Center officials said Cumpler had an outburst in her cottage and had to be restrained. Authorities said her heart and breathing stopped after she had been under restraint for about 25 minutes.

Officials said staffers wrapped her in a mat and placed her on the floor. Then two staff members held her down at the torso and legs while a third wrote down the procedures and how Cumpler was responding.

After she stopped breathing, the facility's paramedics performed cardiopulmonary resuscitation. She was pronounced dead at Beebe Medical Center in Lewes.

"It is a terrible tragedy and I feel bad for the family," said Stockley Superintendent Steven H. Shumacher. "I don't know what else I could say other than that it was just terrible."

Shumacher said he called the family after hearing the results of the autopsy and "wished them Godspeed. It's a terrible tragedy."

William E. Love, acting deputy director of the state Division of Mental Retardation, said an internal investigation is continuing.

"I think all the employees at the facility are distraught over the tragedy," Love said.

Elice J. Roberts, president of the Association of Citizens for the Mentally Retarded, said the Association of Retarded Citizens of Delaware "has serious concerns about the use of any type of aversive therapy" and concerns about the staff training and quality of care not only at Stockley, but all programs of the division.

Attorney General Charles M. Oberly III said his office has been involved "since the very early stages and we have a full investigation going on."

Sussex Bureau reporter Patricia V. Rivera contributed to this article.

Analysts see losses at DuPont

No change expected in Benlate strategy

By NEIL ROLAND
Bloomberg Business News

WILMINGTON — Despite its second trial loss this month, DuPont Co. will press ahead with its litigation strategy in the Benlate fungicide cases and might lose up to $1 billion in the years ahead, analysts predicted Friday.

DuPont wouldn't comment.

A Hollywood, Fla., jury Thursday awarded a Florida grower $3 million for damage to his 71,000 orchids found to have been caused by Benlate 50 DF.

Analysts differed on the effect

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Retarded woman died during mat restraint

By Mike Yaple
Assistant editor

GEORGETOWN – The mentally retarded woman who died Sept. 6 at Stockley Center died of respiratory and cardiac arrest when untrained staff wrapped her in a mat to restrain her, according to state officials.

The state medical examiner's office ruled the death of Marcee Crumpler as stemming from "acute respiratory and cardiac arrest from positional pressure on the upper body due to a restraining procedure," according to Joanne Veto, spokeswoman for the Department of Health and Social Services.

"She was wrapped in a mat as part of a behavioral procedure," said Ms. Veto, adding that some people at the center can become strong and hurt themselves during violent outbursts.

William E. Love, acting director of the Department of Mental Retardation, said the restraining mat is lightweight fabric similar to a bedspread.

Neither he nor Ms. Veto could explain exactly what caused the "positional pressure" that was described by the medical examiner's office.

Health and Social Services Secretary Carmen Nazario requested an investigation after the death.

"There was a lack of training," Mr. Love said, adding there were problems in the facility's supervision and oversight of behavior programs.

He said he has discontinued use of the seven restraining procedures, of which the mat was one. The department has hired a consultant to review Stockley Center's behavior management program. Training for staff will be increased, he said.

State police investigating death of retarded woman at Stockley Center

By PATRICIA V. RIVERA
Evening Journal reporter

GEORGETOWN — A 51-year-old, mentally retarded woman died after being restrained by Stockley Center workers Monday, sparking a police investigation of her death.

Authorities Tuesday released only sketchy information.

Dr. Judith G. Tobin, assistant medical examiner, is expected to release autopsy results today. State police will not comment until they receive her findings, said Public Information Officer Preston Lewis.

Officials said her breathing and heart beat stopped during the 25-minute restraint procedure.

Stockley Center's superintendent, Steven H. Schumacher, who said an internal investigation also is under way, gave an account of the woman whom he would identify only as "Marty G. from Wilmington."

The woman, institutionalized since 1973, had severe mental retardation and was diagnosed as low-functioning, with violent behavior.

Marty had violent outbursts four or five times each year.

"She is a very aggressive person who has hurt many people in her life here."

Restraint procedures had been used without incident during Marty's previous outbursts.

She was the only resident receiving outside counseling intervention.

She lived in a cottage for those with similar behavior problems.

Holiday staffing was at full level Monday at the facility, which has 738 residents and about 700 employees.

Marty was in her cottage when she had an outburst.

"The restraint program was implemented because she is a harm to herself and to others."

That procedure was followed Monday:

■ Staffers wrapped her in a mat and placed her on the floor.

■ Two staff members held her down at the knee and legs.

See STOCKLEY — A8

Stockley: Woman dies at center

FROM PAGE A1

■ A third staffer was present, writing down all procedures and how Marty was responding.

Marty had been under restraint for almost 25 minutes, when she began having difficulty breathing.

The facility's paramedics were called to the scene and performed cardiopulmonary resuscitation (CPR).

The paramedics took her to Beebe Medical Center in Lewes. She was pronounced dead on arrival about 5 p.m.

"Deaths don't happen very often at Stockley, especially not with a 51-year-old ...," Schumacher said. "Now that it has happened there will be an extensive review."

Generally, those who die are older residents with medical complications along with their mental retardation.

Oddly, Schumacher said, Marty's death was the center's second in as many days. A 52-year-old Stockley resident who had been in Beebe hospital for treatment died there Sunday of liver failure.

In addition to the investigations of Marty's death by state police and the Stockley Center administration, an ombudsman from the Court of Chancery is investigating.

Stockley Center is a statewide facility, serving Delaware residents who have severe mental retardation. Many with less-severe mental retardation live in community residences or other placement alternatives throughout the state.

Stockley Center faces citations

Problems found in treatment programs

By JANE HARRIMAN
Staff reporter

GEORGETOWN — Delaware's Stockley Center for the mentally retarded near Georgetown has 45 days to correct serious problems in its treatment programs or lose its certification and eligibility for Medicaid reimbursement.

The deficiencies, which involve a lack of attention to residents and substandard therapies, were uncovered about 10 days ago during a reinspection of the center, according to Joanne Veto, public information director for the Department of Health and Social Services.

Three months ago, the state Office of Health Facilities Licensing and Certification, which inspects health facilities for state and federal governments, cited a number of problems at Stockley, Veto said. Inspectors returned late last month to make sure they were corrected.

They were, she said, but new problems were found.

The administration of the center was given 10 days to submit a plan of correction and 45 days to implement it. If conditions are not up to standard on reinspection, the center will be dropped from Medicaid.

In response, Stockley superintendent Steven H. Schumacher said: "What we're doing ... is reviewing staffing standards in the professional areas of speech therapy, occupational therapy and physical therapy to see if enhanced staffing is indeed required."

Schumacher said the deficiencies cited "have nothing to do with anything life-threatening or life-endangering. However, it's focused on the area of training and the maintenance of skills," or what technically is called "active treatment."

All but 12 of the center's 875 residents are eligible for Medicaid, which means the federal government pays about half of the cost of their care, leaving half for the state. Stockley costs nearly $78,600 a year per resident, or $201 a day.

Veto said the deficiencies point to the need for more staff training, and more time spent caring for residents.

The state is preparing its correction plan, which should be submitted by the end of the week, Veto said.

Staff reporter Chris Donahue contributed to this article.

Stockley Center faces citations

By JANE HARRIMAN
Staff reporter

GEORGETOWN — Delaware's Stockley Center for the mentally retarded near Georgetown has 45 days to correct serious deficiencies in its treatment programs for residents or lose its certification and eligibility for Medicaid reimbursement.

The deficiencies, which involve a lack of attention to residents and substandard therapies, were uncovered about 10 days ago during a reinspection of the center, according to Joanne Veto, public information director for the Department of Health and Social Services.

Three months ago, the state Office of Health Facilities Licensing and Certification, which inspects health facilities for state and federal governments, cited a number of deficiencies at Stockley, Veto said. Inspectors returned late last month to make sure the problems were corrected.

They were, she said, but new problems were found.

In response, Stockley superintendent Steven H. Schumacher said: "What we're doing as far as part of a correction is reviewing staffing standards in the professional areas of speech therapy, occupational therapy and physical therapy to see if enhanced staffing is indeed required."

Staff reporter Chris Donahue contributed to this article.

Evening Times 9/9/93

Antopsy results are pending in Stockley case

By PATRICIA V. RIVERA
Sussex Bureau reporter

GEORGETOWN — Results of an autopsy on a 31-year-old Stockley Center resident who died after being restrained for nearly 25 minutes won't be available for a few days, the state medical examiner said Wednesday.

Medical Examiner Ali Z. Hameil said he is awaiting laboratory results before announcing the cause of Mardee Curmpler's Monday death.

Further police investigation depends on the autopsy report, but an advocacy group for the mentally retarded plans its own look at Stockley's procedures.

If Curmpler — a 20-year resident of the state institution for severely retarded people — died from natural causes, the investigation will not be pursued, said Cpl. David W. Thomas, a state police spokesman.

"But if the results point to some type of criminal act such as murder or negligence, then the attorney general will be contacted," Thomas said.

Curmpler was pronounced dead at Beebe Medical Center about 5 p.m. Monday. After a violent outburst, she had been wrapped in a mat and restrained by two workers — but then her breathing and heartbeat stopped, officials say.

"We are shocked at this tragedy and have some real concerns [about] this occurrence," said Ellen J. Roberts, of the Association for the Rights of Citizens with Mental Retardation.

Roberts said the group plans to meet with Division of Mental Retardation officials to discuss prolonged restraint and other issues.

rday, Sept. 11, 1993 ** Page A 3

News Journal 9-11-93

Stockley workers reassigned

By PATRICIA V. RIVERA
Sussex Bureau reporter

GEORGETOWN — Four Stockley Center employees are being reassigned pending the investigation into the death Monday of a mentally retarded patient who stopped breathing while being restrained by the workers.

Bill Love, acting director of the Division of Mental Retardation, said Friday the workers were placed on administrative leave Thursday and sent home without pay.

The workers, who were not identified, will be allowed to return to the nonpatient care area Monday. Pending the results of internal and police investigations in the death of 31-year-old Mardee Curmpler, the employees could be reassigned to patient care.

The move was too slow for some members of an advocacy group for the mentally retarded.

"We don't understand why action was not taken until Thursday," said Ellen J. Roberts, president of the Association for Rights of Citizens with Mental Retardation. "Stockley clearly has a policy that addresses how there should be immediate removal of a employee when an unusual incident occurs."

Curmpler, a 20-year resident of the state institution for severely retarded people, died after being restrained following an outburst.

The cause of death has yet to be announced. State Police and the Division of Mental Retardation are investigating.

Woman's death investigated at Stockley

Retarded patient died while being restrained

By PATRICIA V. RIVERA
Sussex Bureau reporter

GEORGETOWN — A 31-year-old, mentally retarded woman died after being restrained by Stockley Center workers Monday, sparking a police investigation of her death.

Authorities Tuesday released only sketchy information about the woman's death.

Dr. Judith G. Tobin, assistant medical examiner, is expected to release autopsy results today. State police will not comment until they receive her findings, said Public Information Officer Preston Lewis.

Officials said her breathing and heart beat stopped during the 25-minute restraint procedure.

Stockley Center's superintendent, Steven H. Shumacher, who said an internal investigation also is under way, gave an account of the woman whom he would identify only as "Marty C. from Wilmington."

The woman, institutionalized since 1978, had severe mental retardation and was diagnosed as low-functioning, with maladaptive or violent behavior.

Marty had violent outbursts four or five times each year.

"She is a very aggressive person who has hurt many people in her life here."

Restraint procedures had been used without incident during Marty's previous outbursts.

She was the only resident requiring extreme restraining intervention.

At Stockley, Marty lived in the smallest cottage for those with such behavior problems.

Holiday staffing was at full level Monday at the facility, which has 878 residents and about 700 employees.

Marty was in her cottage when she had an outburst.

"The [restraint] program was implemented because she is a harm to herself and to others."

That procedure was followed Monday:

- Staffers wrapped her in a mat and placed her on the floor.
- Two staff members held her down at the torso and legs.

See STOCKLEY — B

Stockley: Death

FROM PAGE B1

- A third staffer was present, writing down all procedures and how Marty was responding to them.

Marty had been under restraint for close to 25 minutes, when she began having difficulty breathing.

The facility's paramedics were called to the scene and performed cardiopulmonary resuscitation (CPR).

The paramedics took her to Beebe Medical Center in Lewes. She was pronounced dead on arrival about 5 p.m.

"Deaths don't happen very often at Stockley, especially not with a 31-year-old passing away," Shumacher said. "Now that it has happened there will be an extensive review."

Generally, many months elapse between deaths at the center and usually, those who die are older residents with medical complications along with their mental retardation.

Oddly, Shumacher said, Marty's was the center's second death in as many days. A 58-year-old Stockley resident who had been in Beebe hospital for treatment died there Sunday of liver failure.

In addition to the investigations of Marty's death by state police and the Stockley Center administration, an ombudsman from the Court of Chancery is investigating the woman's death.

Stockley Center is a statewide facility, serving Delaware residents only, for people who have severe mental retardation. Many with less-severe mental retardation live in community residences or other placement alternatives throughout the state.

Stockley to present self-reform plans

Director: Problems in survey being addressed

By PATRICIA V. RIVERA
Sussex Bureau Reporter

GEORGETOWN — The state board of health will meet today to consider Stockley Center's plans for correcting numerous deficiencies in care uncovered in an annual survey of the facility.

Stockley Superintendent Steven Shumacher said most of the problems found during the Aug. 3-13 survey of the institution for mentally retarded people are being addressed through improved training, specifically in treatment.

Shumacher has already presented the board with his plan for addressing the problems. The board is scheduled to consider those initiatives when it meets at 2 p.m. in the Jesse Cooper Building in Dover.

Today's meeting comes two weeks after a Stockley patient died while being restrained by staff. Mardee Crumpler, 31, a Stockley resident for 20 years, stopped breathing as staff sought to restrain her after a violent outburst. State officials continue to investigate the circumstances of her death.

The August survey, which the board will focus on today, found Stockley failed to provide continual "active treatment" — everyday skills residents need to live independently — to 67 percent of 54 residents reviewed. The center serves more than 200 people.

According to the survey, staff failed to prompt residents when they were supposed to be busy, failed to stop them from engaging in prolonged self-stimulatory behavior [i.e., incessantly jerking their heads], and failed to interact with residents in an appropriate manner. For instance, staff would seek to solicit verbal replies from nonverbal residents.

Shumacher said QA Group Inc., an Ohio-based consulting firm, last week conducted a four-day in-house training session on active treatment to staff.

He said the training was a short-term solution, but to address the problems adequately the center will seek guidance from similar facilities throughout the country.

Stockley is operating on its second 90-day provisional state license. The state board of health pulled the facility's annual license in May after Stockley failed its second inspection.

If the problems continue uncorrected or if the facility's plan is not approved by Oct. 1, Stockley could lose $11 million in federal Medicaid funding, about half its budget.

Joanne Veto, public information director of the Department of Health and Social Services, said the deficiencies identified in the most recent survey are drastically different from those identified in a March survey — the report that prompted the state to rescind the facility's annual license.

The March survey, among other deficiencies, found residents were having sex with each other, and untimely reporting of resident abuse or neglect.

"Patient care, health and safety have been taken care of," Veto said.

Other problems noted in the August survey:

- Failure of a Stockley committee to investigate incidents of suspected client abuse, neglect or mistreatment in a timely fashion.
- Stockley's failure to get written permission from legal guardians to use certain restraint procedures on violent residents.
- The center's failure to show the staff is trained in controlling communicable disease.

STATEMENT OF THE CHILD WELFARE LEAGUE OF AMERICA

The Child Welfare League of America (CWLA) is grateful for the attention to the use of seclusion and restraints and strongly supports the establishment of national standards to care safely and appropriately for children and young people. These complex issues directly affect the safety of children in care and the safety of staff who provide care. It is essential that legislation be thoughtfully developed. Our response to abuses in the use of seclusion and restraints must not undermine sound practices critical to insuring the safety and well-being of children and staff.

CWLA is an 80-year-old association of more than 1,000 public and private nonprofit community-based agencies that serve more than three million children, youth, and families each year. Member agencies provide services for the prevention and treatment of child abuse and neglect, as well as child protective services, family preservation, family foster care, residential group care, adolescent pregnancy prevention, child day care, emergency shelter care, independent living, youth development, and adoption. Setting standards and improving practice in all child welfare services have been major goals of the Child Welfare League of America since its formation in 1920. Nearly 600 of our member agencies provide residential services.

The Children in Residential Care:

Children in residential group care today have complex problems. They often show violent behaviors, multiple diagnoses, severe learning disorders, and an increased frequency of alcohol and drug addiction. Typically, children and youth in these facilities have histories characterized by instability, abuse, neglect, and rejection.

Most of the children and young people we serve have had horribly sad lives. They are angry, they are depressed, and they act out. For many youths, their placement into residential facilities very often is their last chance at social services before a move into the juvenile justice system. For younger children, their successful placement in residential and group settings prevents them from being hospitalized in more institutional settings. The legislation as currently drafted will severely limit appropriate staff options needed to protect children, will sometimes jeopardize children's safety, and may force young people into more restrictive settings.

Residential Care:

Unlike hospitals, residential group care is based on a non-medical model and very purposely so. On the whole, residential group care is meant to provide children with a safe, nurturing, protective, therapeutic environment while addressing their unique educational, social, behavioral, developmental, medical, and emotional needs. These facilities were developed as step-down, less intensive, non-medical means to keep children in their communities. Just as in private families, physicians are not a part of daily interaction and behavior management. Direct care workers are the primary care givers and have the day-by-day, hour-by-hour involvement in the lives of the children.

CWLA Concerns about Pending Legislation:

1) Need for definitions:

- Pending legislation seeks to extend a provision for nursing homes to cover people with a range of conditions, from birth to death, in medical facilities as well as non-medical facilities that provide behavioral health care.
- "Physical restraint" is defined broadly and fails to distinguish between physically holding a child and the use of mechanical restraints. There is no way to distinguish a reassuring hug from a restraint.
- Seclusion is defined broadly to include locked isolation and time-out. Time-out is the separation from the group, in a non-locked setting, for the purpose of calming.
- There is no explanation of when a standard medication becomes a chemical restraint. It presumes that there is a clear line between a medication used for disciplinary purposes and when it is related to a patient's medical condition. The line between is very vague and a potential area of abuse.

2) The requirement that a "physician or other licensed independent practitioner" order the use of seclusion or restraint fails to insure that the responsible person will have the necessary and appropriate skills, knowledge and expertise. Standards should designate the responsible person not by title but rather by a mastery of experience and knowledge in matters including behavior management, de-escalation, health concerns, restraint techniques, and use of seclusion and restraints.

CWLA Practice and Policy Recommendations to Protect Children in Care:

- Restraints and seclusion must only be used to ensure the physical safety of the child and all others and should never be used for purposes of discipline and convenience.
- The use of chemical restraints, mechanical restraints, and locked, isolated seclusion for children and youths must be prohibited.
- There should be mandatory reporting of behavioral interventions, such as seclusion and restraints, within 24 hours.
- All staff must receive appropriate initial and ongoing training in behavior management, de-escalation, and the use of seclusion and restraints, including less intrusive interventions and emphasis on the medical, legal and other implications of the use of restraints.
- Any legislation must support the development of national guidelines and standards on the quality, quantity, orientation and training, as well as the certification of those staff responsible for the implementation of behavioral intervention concepts and techniques.
- Proposed remedies must include a plan to address the workforce crisis confronting children's service organizations throughout the country in the recruitment and retention of qualified direct care practitioners. The goal of establishing a licensing, certification, and credentialing standard for direct care workers is of primary importance.
- States should be required in their licensing, contracting, and regulation to include reporting and analysis of restraints on a regular basis, to set minimum expectations about staff development, and to make expectations consistent between public and privately operated facilities that serve the same children and youths.

COMMONWEALTH OF PENNSYLVANIA, DEPARTMENT OF PUBLIC WELFARE

[SUBMITTED BY CHARLES CURIE, DEPUTY SECRETARY FOR MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES]

Thank you for providing me with the opportunity to submit written testimony on the important matter of the use of seclusion and restraint in psychiatric treatment facilities and for the opportunity to share Pennsylvania's experience with these high-risk techniques in our nine state mental hospitals. My name is Charles Curie, and I am the Deputy Secretary for Mental Health and Substance Abuse Services (OMHSAS) in Pennsylvania's Department of Public Welfare.

Seclusion and mechanical restraints have been used in institutions for persons with mental illness since the 16th century, to contain the behavior of persons who were perceived by caretakers to be potentially violent, destructive of property, disruptive of institutional routine, suicidal, self abusive, or simply to control their freedom of movement and activity.

In the 1990s, the second generation of atypical antipsychotic medications, which addresses the positive symptoms of Schizophrenia (hallucinations, delusions and thought disorder), as well as the negative symptoms (apathy, flat affect, poor concentration, etc.), has decreased the percentage of persons with SMI who require hospitalization. The effectiveness of several of the new, atypical antipsychotics in specifically targeting violent, assaultive and aggressive behavior has also reduced the percentage of patients for whom seclusion and restraint remain the option of last resort.

In 1985, the daily census of the state mental hospitals in PA averaged 8,364 patients. That year, over 46 hours of seclusion were employed for every 1000 patient days. By 1994, hospital census had been reduced to 5,162 patients and seclusion and restraint use had declined to 33.5 hours per 1000 patient, days. Between the end of 1994 and the end of 1998, the average number of seclusion hours fell to 2.88 hours per 1000 patient days, as the hospital census declined to 3,300.

A corresponding decrease in the number of hours of restraint per 1000 patient days was also experienced during those years, from 61 hours per 1000 patient days in 1992/93, to 40 hours by the end of 1994, and to 18.6 hours by January 1, 1999.

I'd like to describe to you the story behind the dramatic reduction in Pennsylvania's use of seclusion and restraint, the conditions that had to be met before reduction and elimination could be systematically pursued, and the administrative and clinician strategies and steps taken toward achievement of this goal.

First, a variety of specific conditions must be met before systematic reduction and control of the incidence and duration of seclusion and restraint can be successful.

1. Staffing adequate to meet patient treatment needs at the appropriate level of patient acuity is necessary before seclusion and restraint use can be reduced. When the number of patients was double that of staff in the Pennsylvania SMH system in the 1970s, seclusion/restraint use was considered to be treatment, and its use was endemic. However, since the mid 1990s, OMHSAS hospitals have averaged a 2 staff to 1 patient ratio, sufficient to provide active intervention and treatment with minimal use of these procedures.

2. Staff needs adequate and regular training in verbal crisis management techniques and safe physical management. Use of training programs developed by reputable training sources, whose techniques adhere to current best practice and have proven efficacy, is essential. Staff must be able to demonstrate competency in the use of these techniques before they are permitted to employ them.

3. The availability of regularly scheduled, meaningful treatment programs to help patients to develop skills and abilities needed for community integration is essential. Active treatment that gives patients choices among useful, pleasurable, desirable and productive activity, such as that found in "treatment malls," fosters the patient's partnership in treatment, reduces frustration and rage, reduces the interpersonal tensions and boredom developed in a closed living area, reduces confrontations among patients, and between patients and staff, that once often resulted in seclusion and restraint. It also increases patient competence to manage stressors, confidence in their ability to succeed; more tolerance of delayed gratification, and it fosters hope!

4. Active risk assessment and risk based treatment Planning must be in place. Violence very seldom occurs in a vacuum, without context or situational cause. When patients are thoroughly and systematically assessed at admission and at monthly intervals for past and present behavioral risks for violence, substance abuse, self harm and other variables that may create danger to self or others, and the contexts in which these behaviors have occurred in the past have been identified, individual treatment plans can be developed to help patients avoid or manage these precipitants in very concrete and targeted ways.

5. Availability and use of the second generation, antipsychotic medications, developed since the early 90s, improves the psychiatrist's ability to effectively treat both the positive and negative symptoms of mental illness without Extra Paramidal Symptoms (EPS) and other undesirable side effects. Several of these medications are especially helpful in targeting impulsive, assaultive and aggressive behavior. In PA 's state mental hospitals, 72 percent of all patients are receiving second generation anti-psychotics, a percentage that has steadily increased since the mid- 90s.

6. An environment of care that promotes patient comfort, dignity, privacy and personal choice must be created. The more rules staff impose and the more those rules appear to be arbitrary and designed to meet staff needs, the higher the incidence of seclusion and restraint is likely to be. Our hospital and central office staff work closely with the clients rights advisors and independent client advocates to identify and abolish arbitrary ward rules and prohibitions, improve the environment of care, and resolve patient grievances before they escalate to crisis.

7. At the state level, aggregate data about each hospital's incidence and hours of seclusion and restraint has been collected monthly, since October 1997, and multi-hospital, longitudinal comparisons of this data are systematically represented in performance indicator graphs. These indicators are now transmitted to JCAHO on a quarterly basis, as part of the Joint Commission's ORYX requirement. These performance indicators are freely shared among hospitals, posted on ward bulletin boards, disseminated to NAMI of PA, other advocates, Pennsylvania Protection and Advocacy, to the OMHSAS Planning Council, other State Mental Health authorities, and will soon be posted on a new OMHSAS WEB page.

OMHSAS closely monitors each hospital "outlier," which is clearly displayed on the performance indicator graphs. Improvement (i.e., reduction in use and duration) is reinforced; lack of improvement is queried and addressed. As incidence has declined, we have noted that seclusion and restraint use now appears to be confined to a very small sample of patients, about .01% of the population, and that most hours of use can be attributed to 1 or 2 patients at each facility. Now that heavy users can be systematically identified, OMHSAS and hospital clinical directors routinely conduct statewide peer reviews to develop more effective treatment approaches for these difficult patients, and independent consultants are more likely to be utilized.

The role of leadership and the timing and manner of setting goals and objectives regarding seclusion and restraint reduction, and ultimately elimination, cannot be underestimated. Declaration of a unilateral ban on use of seclusion and restraint from the top down, if the resources enumerated above were not in place, would probably not succeed.

I announced the long-range goal of eliminating seclusion and restraint in mid 1998, when I believed it was an achievable goal for Pennsylvania, and when the conditions described above were in place. The goal has the strong and committed support of OMHSAS clinical and administrative leadership and family and consumer advocacy organizations.

However, accomplishment of this goal meant the necessity for a change in attitudes and beliefs about seclusion and restraint at all levels of the organization. These changes have to be accompanied by the system wide belief that elimination of seclusion and restraint is both the right thing to do for patients and a safe course of action for staff. Staff must also have the confidence that they do possess the skills, resources and supports to accomplish this goal. These are tough attitudes to change.

One of our first steps in PA was to change that label to ensure that seclusion and restraint were defined as safety procedures, not as treatment or a substitute for treatment. Their use meets none of the definitions of treatment. They do not alleviate pain, do not control symptoms, do not prevent exacerbation of the illness, and they do not heal or cure. The scope of use was then limited to emergencies, only for those circumstances in which the patient's behavior presented a clear and present danger of bodily harm to self or others, when all treatment measures had already been considered, tried and failed. Use for disruptive behavior or verbalizations, threats, property damage, disobedience, failure to adhere to ward rules or as punishment for infractions was eliminated. Subsequently, entry of minute details regarding every instance of use into a centralized data bank limited the reporting options to the circumstances just described. These measures alone accounted for much of the decline in use during the mid-1990s.

Secondly, the duration and safety of use also had to be addressed. Consequently, OMHSAS adopted stringent policy and procedural guidelines for the use of seclusion and restraint, with extensive input from clinical leaders at the hospital level. These policies exceed the current standards for use of these procedures established by the JCAHO. These policies mandate that a physician's order for seclusion and restraint cannot exceed one hour, and that the physician must examine the patient within 30 minutes each and every time the order is renewed for one-hour intervals. Furthermore, one hour is viewed as the outside limit; patients must be removed from seclusion and restraint as soon as the crisis has passed. Persons in restraint must be under constant and direct staff observation. The type of restraint and body position of the patient in restraints must be determined by the physician in the context of the patient's condition, including consideration of medical risk factors. Best practice guidelines for avoidance of injury during the physical management and mechanical restraint of patients have been developed and issued, which address body position and clinical risk factors involved in its use. Patients must be debriefed at the end of the procedure and the treatment plan must be reviewed and revised to address the underlying treatment needs of the resident.

Under the new statewide policies, every instance of seclusion and restraint use is monitored for adherence to policy and best practice through the OMHSAS' incident reporting system and its performance improvement system. Each incident automatically triggers internal review by the Quality Improvement Director and the CQI Committee and by the hospital executive staff including the Clinical Director, and Nursing Director and Superintendent.

Under the above circumstances, seclusion and restraint are unlikely to be used for staff convenience or other non-essential purposes. These procedures also place accountability for seclusion and restraint use under the active leadership and control of the psychiatrist, who also must assume responsibility for developing treatment programs that address the precipitants of seclusion and restraint incidents.

Changes in policy regarding the use of seclusion and restraint were essential, but not before staff could view such changes as manageable and desirable. When the time came, statewide workgroups of clinical leaders, CQI Directors, nurses and managers were convened to develop policies for use of seclusion and restraint, promoting a sense of ownership by hospital staff and a willingness to test the limits.

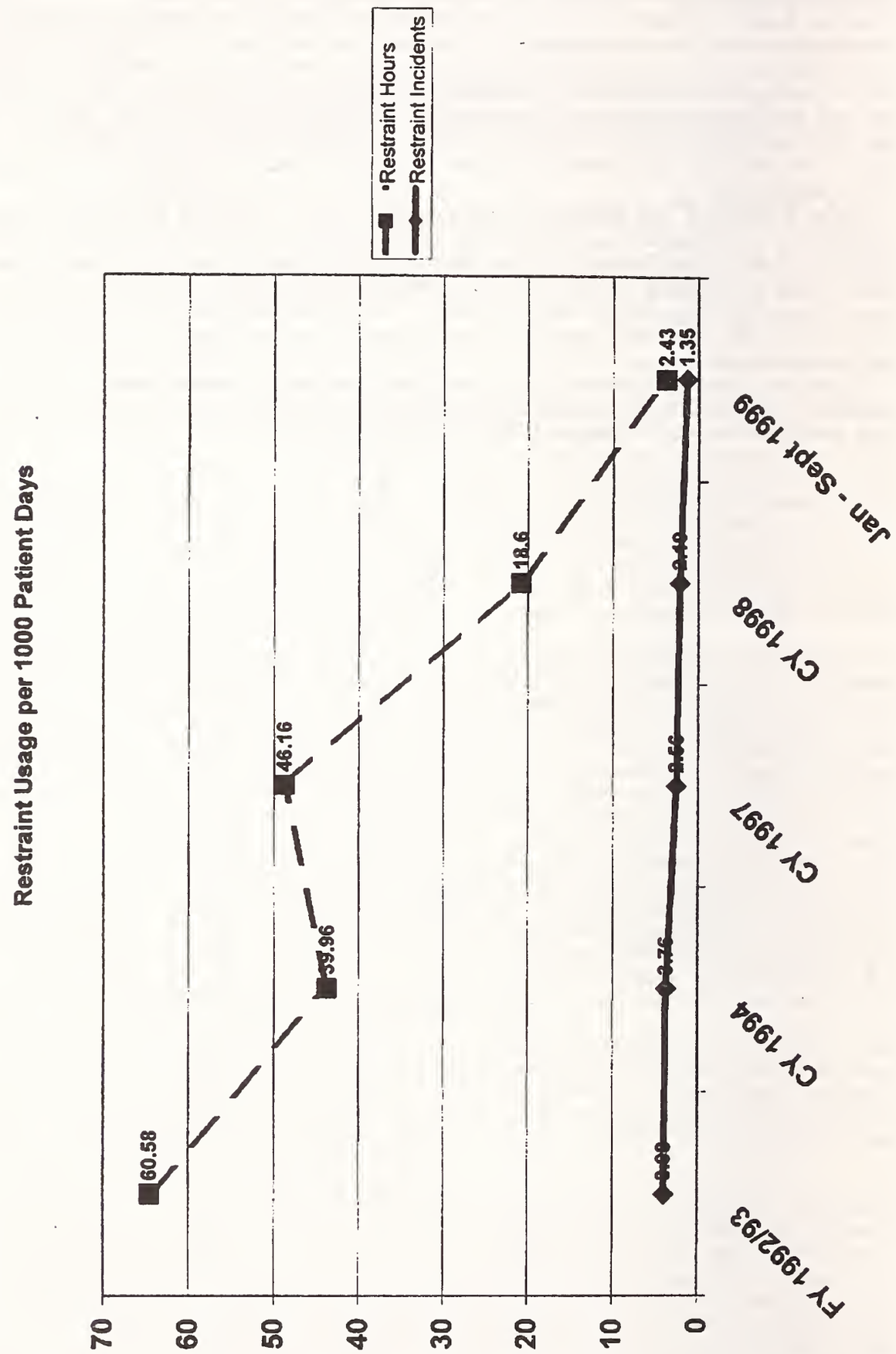
Hospital leadership has been encouraged to use these new policies as a baseline on which to develop even more stringent seclusion and restraint use practices, and to set target dates for the total elimination of their use. Closure of ward seclusion rooms, creation of specialty wards for intractable patients, greater use of statewide, physician peer review consultation and independent expert consultants, and shorter

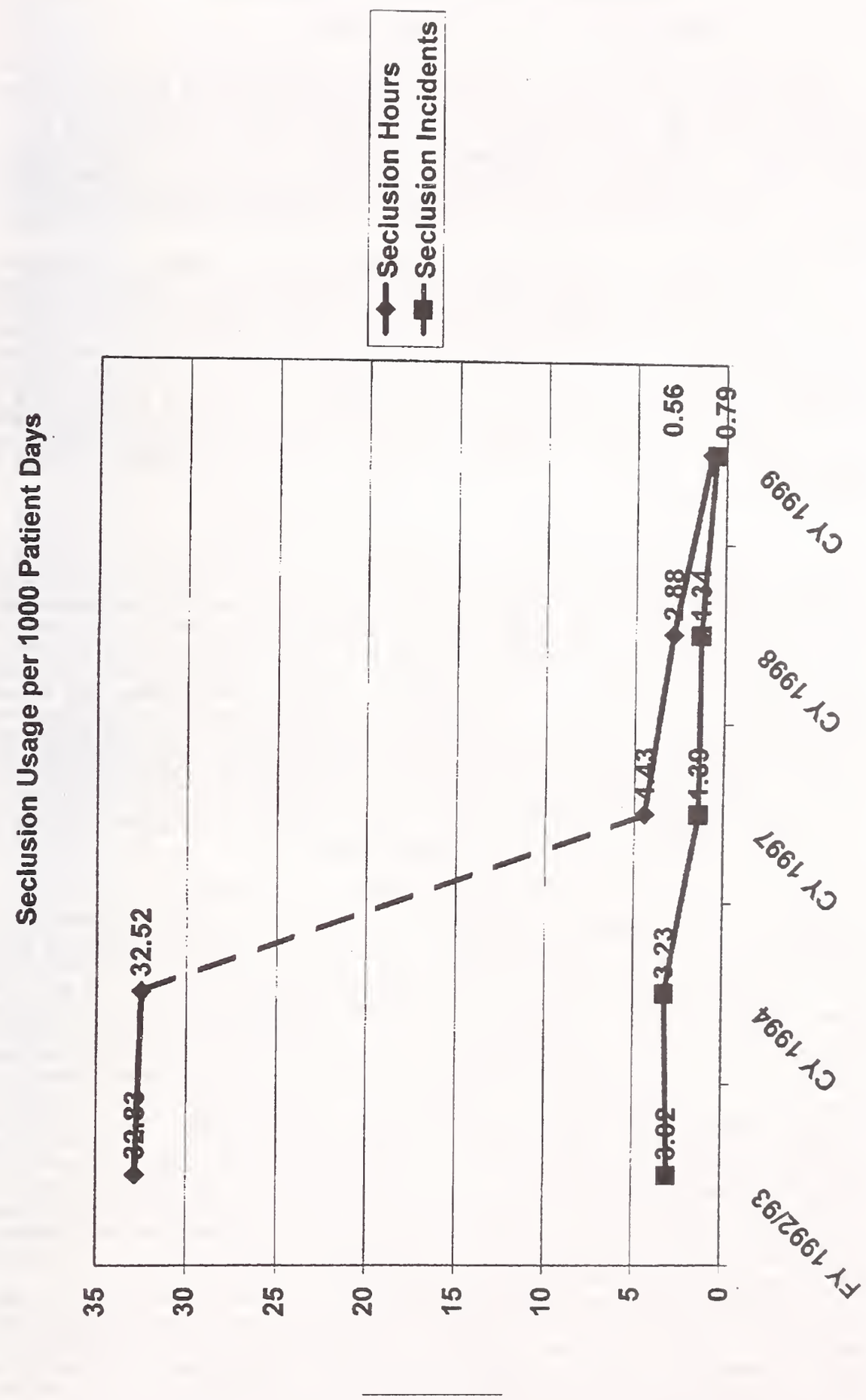
permissible periods of seclusion and restraint are only a few examples of individual hospital initiatives developed to further curtail use of these practices.

As we progress toward our goal, we continually reinforce the need to curtail and continually reduce the use of seclusion and restraint with both clinical and administrative managers at each hospital, and a healthy atmosphere of competition to find better methods to control crisis situations is emerging. Concurrently, ward staff has learned that the frequency and severity of staff injuries has declined as use of seclusion and restraint decreases. Staff also feel safer in an environment where physical confrontation is not the norm, and more confident about their ability to treat patients effectively.

I hope I have left you with two clear messages today. First, the time to begin the elimination of seclusion and restraint in psychiatric facilities has commenced. It is possible. It is doable. Second, this change must occur as a process; it cannot be accomplished by ordering its occurrence or merely altering policy and imposing sanctions. Improved knowledge and technology, leadership and attitude change, adequate resources, staff skill, training and innovation are as essential to this process as policy change.

Thank you for the opportunity to speak with you about Pennsylvania's endeavor to curtail, control and ultimately eliminate the use of seclusion and restraint. I hope that this information will be useful to your deliberations.


Restraint Usage per 1000 Patient Days
Restraint Hours
Restraint Incidents
70
60
50
40
30
20
10
0
60.58
46.16
39.96
18.6
2.43
1.35
FY 1992/93
CY 1994
CY 1997
CY 1998
Jan - Sept 1999


Seclusion Usage per 1000 Patient Days
Seclusion Hours
Seclusion Incidents
35
30
25
20
15
10
5
0
32.52
4.43
2.88
0.56
3.23
1.39
0.79
FY 1992/93
CY 1994
CY 1997
CY 1998
CY 1999

Statement of the Devereaux Foundation

[SUBMITTED BY RONALD P. BURD, PRESIDENT AND CEO]

The Devereux Foundation appreciates this opportunity to submit its views on the use of seclusion and restraints in mental hospitals and related clinical settings. Founded in 1912, Devereux is the largest non-profit provider of mental health services to children in the United States, active in twelve states and the District of Columbia. Devereux provides care to clients of all ages in the most clinically appropriate and least restrictive environments available, and has developed a reputation for the successful treatment of the most profoundly challenged individuals with diagnoses of mental retardation, developmental disability, and emotional and behavioral disturbance.

We at Devereux commend the Senate for paying attention to persons, and particularly children, who are challenged by developmental disability or emotional disturbances. These people are among the most vulnerable in our society, often mistreated by others in society, by public institutions charged with their care, and at times sadly even by their own family. Improper seclusion or restraint of these individuals is unacceptable to The Devereux Foundation. Ensuring that clients receive the most appropriate and humane treatment services in the least restrictive environment is the first priority of our therapeutic programs. While the bulk of our testimony will focus on possible unintended consequences of recent legislation addressing seclusion and restraint policies, we wish to emphasize that we share the intent and goals of this hearing and those bills.

I. REGULATORY AND LEGISLATIVE BACKGROUND.

As you know, Senator Dodd introduced S. 750, the Compassionate Care Act of 1999, and Senator Leiberman introduced S. 736, the "Freedom from Restraint Act of 1999," on March 25, 1999. On July 2, 1999, the Health Care Financing Administration ("HCFA") issued an interim rule establishing six standards in this area to which hospitals participating in the Medicare and Medicaid programs must conform. 64 Fed. Reg. 36070 (July 2, 1999). On July 28, 1999, a version of the Dodd and Leiberman bills was added as an amendment to S. 976 (the Youth Drug and Mental Health Services Act), and this legislation was reported to the Senate by the Committee on Health, Education, Labor and Pensions on October 19, 1999. In September of 1999, the General Accounting Office issued a report entitled, "Mental Health: Improper Restraint or Seclusion Use Places People at Risk" (GAO/HEHS–99–176).

Devereux filed comments on the HCFA rule on August 30, 1999, which are attached to this testimony. We have reviewed the GAO Report, S. 736, S. 750 and S. 976 and would like to present the following comments.

II. GENERAL POLICY ON SECLUSION AND RESTRAINT

Recent reports of death or injury during the implementation of seclusion or restraint have led many behavioral health providers to a careful re-evaluation of practices, standards and policies regarding the use of either procedure. Along with family members and consumers of care, we at Devereux believe there is no place for abuse in either procedure and have an established policy that each may only be used in the extreme circumstances of danger to self or others. For over fifteen months, a Devereux Task Force has been examining the best practices for the use of seclusion and restraint with each client group we serve. This task force complements our current crisis prevention and intervention training program and related staff development activities. Our goal is to educate all of our staff to avoid the use of seclusion and restraint whenever possible. We provide the comprehensive "New Directions" training program to teach all direct care staff such skills as establishing therapeutic relationships, conflict resolution, and limit-setting. In addition, we provide extensive initial training and at least annual updates on crisis prevention and intervention. As part of our comprehensive Quality Management program, the trends and patterns in the use of both procedures are examined and opportunities for improvement are identified and acted upon.

These many activities have led Devereux to a greater level of understanding about the very real challenges presented by the individuals we serve. Many of these individuals have experienced chaos and pain in their lives, and have learned to deal with the world by using a variety of physically and verbally aggressive behaviors. They sometimes turn their anger and hopelessness inward, and harm themselves or attempt to end their own lives. While our programs mandate the use of the least restrictive intervention possible, there are occasions when the only alternative may be to use a safely implemented physical restraint or a seclusion in order to alleviate the danger to self or others. The client is assisted through the crisis, and continues

through the treatment program to learn how to control his/her behavioral choices. In consultation with our medical personnel, we rely heavily upon our trained and supervised interdisciplinary staff to respond appropriately to the crisis and to work with the client to avoid a recurrence.

We understand that some in the mental health community have proposed that patients be transferred immediately to an acute care setting if they pose risks of injury to themselves or others that would require their restraint or seclusion. We have significant concerns about the disruptions in treatment that would occur if this became the general policy. Indeed, this suggestion is contrary to the general trend in psychiatric care of the past few decades, where individuals are placed in the least restrictive environment possible. We are also concerned about the potential dangers this suggestion presents for the client and those around him or her by delaying an appropriate response to dangerous behaviors. Rather than improving the treatment of individuals exhibiting dangerous behavior, we believe this suggestion may have the unintended consequence of forcing some of the most psychiatrically and behaviorally impaired persons under 18 into juvenile justice settings. When the crisis has passed and the client no longer meets the criteria for the acute care setting, where would they go for necessary continued care? Even if a life-threatening crisis has been averted, it is not as if these individuals are ready for re-entry into society. After release from an acute-care facility, it is not clear that these individuals would be accepted into behavioral healthcare settings if severe restrictions on behavioral management procedures prevent further, necessary therapy.

One additional general policy point should be made at this point: seclusion and restraint policies for individuals **over** 21 years of age are not necessarily appropriate for persons **under** 21. We commend HCFA for recognizing this point by issuing a first interim rule that does not include the under-21 population. S. 736, S. 750 and S. 976 do not make this critical distinction, however, and we will discuss this problem at length in our comments on those bills. We believe a useful and productive dialogue has been established between HCFA and providers of care as the agency attempts to craft the under-21 regulation. We encourage Congress to give this dialogue time to yield results before it legislates in this area.

III. POTENTIAL UNINTENDED CONSEQUENCES OF S. 736, S. 750 AND S. 976

While we concur with the objectives and intent of these bills, there are significant flaws that must be fixed if the bills are not to have significant, adverse unintended consequences. Because S. 976 is in essence a blend of S. 736 and S. 750, I focus my comments on the latter two bills.

1. Lack of Specific Definitions.

Both bills condition a provider's ability to accept Medicaid funding on the provider documenting that each patient shall be free from: (A) "any involuntary seclusion," and (B) "any physical or chemical restraints imposed for purposes of discipline or convenience." The quoted language raises a host of questions for Devereux in its role as one of the leading providers of residential treatment for children with severe emotional disturbances.

The term "involuntary seclusion" could be read to draw no distinction between: (1) an intervention widely used by parents to separate an angry child from his peer group until he has calmed down, and (2) a locked seclusion which might be utilized as an intervention in a behavioral health care setting. S. 736 appears to ban any involuntary seclusion whatsoever—including a "time-out;" S. 750 bars such seclusion when it is imposed "for purposes of discipline or convenience, and that is not required to treat a medical symptom." As stated earlier, Devereux treats a large number of impaired children. An important aspect of our therapeutic approach is to reintegrate the child into social groups, and ultimately into society as a whole. Just as parents of children without such impairments at times must remove a child "involuntarily" from their peer group until a fit of anger has passed, so must the licensed professionals at Devereux sometimes remove a child from a group therapy session until he or she has calmed down. S. 736 would appear to ban this practice outright. S. 750 could effectively ban it as well, since each such removal would have a "therapeutic" but not necessarily a "medical" justification. Denial of this important behavioral technique to providers such as Devereux will slow the reintegration of these troubled children into society as a whole.

The phrase "any physical or chemical restraint imposed for purposes of discipline or convenience" is similarly troubling. Both bills use the all-inclusive term "any" restraint, and S. 750 clarifies that restraint includes "any mechanical or personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely" (emphasis added). It is a disturbing reality that a number of Devereux patients are under the age of 10. Should an intervention such as

holding a smaller child carefully until calm in order to demonstrate physical support for his efforts to achieve control require the same level of medical oversight as the use of chemical or mechanical restraints? Should the holding apart of two children who begin fighting (but do not yet threaten serious injury to each other) require a physician's order? We think the clear answer to both questions is "no," but unfortunately all bills appear to require the opposite answer. The result, again, is to inhibit the use of humane, effective treatment techniques for troubled children.

2. Physician Orders.

All bills prohibit imposition of physical restraints without a written order of a physician. This is a burdensome and overly broad requirement that will have adverse impacts on our ability to provide needed therapy to children. As noted in the example above, requiring a physician's order for a therapist to hold a child until calm poses a tremendous inconvenience and is wholly unnecessary. This requirement would also be detrimental to another standard therapeutic setting. a field trip to a public place. Such trips are important attempts to reintegrate a child into outpatient settings as promptly as possible. On occasion, a child must be restrained by hand to prevent their running away or running into a street full of oncoming cars. Under both bills, a physician's order would be necessary in order to impose this sort of "restraint." Indeed, the number of potential "physical restraints" for which these bills would require a physician's pre-authorization are so numerous that a field trip might be taken off of the list of therapeutic activities—which would be a tragedy for the children.

On a more general level, we also object to the requirement that seclusion and restraints may be ordered by a physician, only. This requirement is difficult enough in a hospital setting. Because S. 736, S. 750 and S. 976 apply also to residential treatment centers, the requirement is simply unworkable. Devereux employs an interdisciplinary group of skilled professionals, each of whom must complete a rigorous credentialing process, to implement our clinical programs and to work with individuals in care. Each treatment team member provides vital input into the treatment planning process and has significant awareness of the client's ever-changing condition. Particularly in our rural and non-hospital programs, these professionals work in consultation with the physician to deliver the prescribed care and to respond to crisis occurrences. They have daily contact with the client and can provide additional understanding regarding the least restrictive methods that may be utilized to provide the most appropriate response to an emergent situation. In consultation with the nurse and with the physician as necessary, the "licensed independent practitioner" provides proper guidance regarding the therapeutic approach and the criteria for release or continuation of the child from seclusion or restraint. In short, not only is 24-hour, on-site physician coverage unfeasible (particularly in the many states with vast rural areas), but it might not achieve the result in which all parties are interested—the least restrictive initial setting, or the most prompt release from seclusion or restraint, as is possible.

3. Disclosure and Reporting Requirements.

Any organization that accepts publicly funded patients, including Devereux, understands that recordkeeping and reporting requirements are a fact of life. The critical issue here is striking the appropriate balance between necessary paperwork and unduly burdensome paperwork. Given recent constraints on public funding of health-care, it is a truism that the more time staff take to comply with recordkeeping requirements, the less time they have to provide care to patients.

S. 750 in particular establishes unnecessary and overly burdensome reporting requirements. It requires a report to the relevant state or federal agency of any "sentinel event," where such event:

> means an unexpected occurrence involving an individual in the care of a provider of services for treatment for a psychiatric or psychological illness that results in death or serious physical or psychological injury that is unrelated to the natural course of the individual's illness or underlying condition.

Devereux agrees that reporting in the event of death is appropriate. It is unnecessary, however, to require mandatory reports for any serious physical or psychological injury "unrelated to the . . . individual's illness or underlying condition." First, it should be noted that this requirement applies to any injury, whether or not caused by the use of seclusion or restraints. Second, this overly broad phrasing could require regulatory reporting if a child enters a Devereux facility with a serious emotional disturbance and, in the course of recreational activity, falls down and fractures an arm or leg. While such an accident is unfortunate, it in no way should require detailed reporting to a governmental regulatory body.

S. 736 would require a facility to report to non-governmental "protection and advocacy" entities the name of any person who dies at the facility and the circumstances of the death. While Devereux agrees that reporting to a governmental regulatory body in the event of a death is reasonable, we have strong privacy and patient confidentiality concerns over the reporting of such an event to any non-governmental, advocacy organization. A death is a horrible personal tragedy, and the rights of the family should be paramount in this situation. In such a situation, the families often object to inserting another entity with which they must deal during a very trying time. Devereux believes that any statute that preempts the right of the family to decide whether a death should be disclosed to other than public officers is inappropriate.

IV. COMMENTS ON OTHER TESTIMONY.

Training. We agree with the comments of a number of witnesses that proper and sufficient training is critical to a humane and effective regime of therapy. Devereux has developed two training curricula in recognition of the importance of training: (1) New Directions, to train direct-care staff on alternatives to seclusion and restraint, and (2) Devereux Crisis Prevention/Intervention, which provides training in the proper techniques when seclusion or restraint must be utilized. We would be happy to share this material with the Committee if that would be helpful.

S. 750 and S. 976 both require covered facilities to provide appropriate training to their staff in the use of restraints (and in any alternatives to such use). While the above curricula demonstrate Devereux's recognition of the importance of staff training, I should emphasize that the current cost-based funding model of the federal programs covered by these bills provides inadequate support for training. If Congress were looking for consensus legislation to enact while the HCFA regulatory process proceeds, increased funding of training in seclusion and restraints would be the ideal topic.

HCFA Regulations. HCFA Deputy Administrator Michael Hash testified about the intensive, multi-disciplinary work effort undertaken to draft the interim regulations for the Hospital Conditions of Participation, and of the ongoing effort for the expected regulations for the under-21 benefit. Devereux has participated in this regulatory effort and urges Congress to allow HCFA to complete this process before legislating in this area.

Pennsylvania Regulations. A number of witnesses, and the GAO Report, note with approval recent regulations on seclusion and restraint from the State of Pennsylvania's Department of Mental Health that have dramatically reduced the number of "restraint and seclusion hours" between 1993 and 1999. Because Devereux is headquartered in Pennsylvania and operates [seven] facilities in this state, we are familiar with these guidelines. It is important to note that Chapter 3800 of Title 55 of the Pennsylvania Administrative Code, applicable to residential treatment facilities for the under-21 population, diverges markedly from the legislative proposals before this Committee. For example:

- "Exclusion"—described as "removal of a child from the child's immediate environment and restricting the child alone to a room or area"—is expressly permitted under reasonable conditions, and is not included in the definition of "seclusion;" if a staff person remains in the exclusion area, such removal is not even an exclusion; 55 Pa. Adm.Cd. §3800.212;
- A "manual restraint" is permitted but limited to ten minutes in duration, after which the need for further restraint must be re-evaluated and the position changed if further manual restraint is required; 55 Pa. Adm.Cd. § 3800.211;
- A "manual assist of any duration for a child during which the child does not physically resist or a therapeutic hold for a child who is 8 years of age or younger for less than 10 minutes during which the child does not physically resist" does not constitute a manual restraint; 55 Pa. Adm.Cd. § 3800.211(a);
- A "physical hands-on technique" that lasts for less than one minute is not a manual restraint; Ibid.

These provisions recognize the unique conditions under which care to the under-21 population is provided. We are encouraging HCFA to adopt this approach in its rulemaking on the under-21 population. S. 736, S. 750, and S. 976, however, make no such distinctions. If Congress chooses to act in this area, we believe it is essential that similar distinctions be made.

V. CONCLUSION.

The Committee is to be commended for paying attention to persons with developmental and emotional impairments that make them some of the most vulnerable people in society. Devereux tries to improve the lives of these people on a daily

basis. We understand that S. 736, S. 750 and S. 976 are sincere attempts to improve the quality of life of these individuals. We respectfully point out, however, that portions of all bills pose serious risks of degrading the quality of the treatment available to the population with which we are concerned. A regulatory process has begun to address these problems which, if not perfect, should be allowed to run its course. If Congress insists on legislating in this area, we strongly suggest that you first come visit a Devereux facility, review the challenges we face every day, and then work with us to develop more acceptable legislation.

Thank you for this opportunity to comment.

Devereux

Arizona
California
Connecticut
District of Columbia
Florida
Georgia
Maryland
Massachusetts
New Jersey
New York
Pennsylvania
Tennessee
Texas

August 30, 1999

Ms. Nancy-Ann Deparle
Administrator
Health Care Financing Administration
Department of Health and Human Services
Attention: HCFA-3018-IFC
P.O. Box 7517
Baltimore, MD 21207-0517

Dear Ms. DeParle:

I am writing today on behalf of The Devereux Foundation to comment on the proposed Standard for Seclusion and Restraint for Behavior Management (42 CFR 482.13 (f)).

The Devereux Foundation, founded in 1912, provides care to a broad age-span of clients in the most clinically appropriate and least restrictive environments available to meet their assessed needs. Throughout our many years of operation, we have developed a reputation for the successful treatment of very challenging mentally retarded/developmentally disabled, emotionally disturbed and behaviorally challenged individuals. Devereux operates a full continuum of services, including acute care psychiatric units, campus-based residential treatment centers, outpatient clinics, and group homes. We provide these services in twelve states and the District of Columbia.

First and foremost, please let me say that we support the overall goals of the "restraint and seclusion" regulations. Ensuring that clients receive the most appropriate and humane treatment services in the least restrictive environment is the first priority of our therapeutic programs. Our system of care is, in turn, supported by both internal and external processes. In addition to state and national accreditation/certification visits, the Devereux Foundation has developed a Clinical Standards Manual which emphasizes our expectations for a strenuous initial staff orientation program as well as continuing education in the areas of direct client care. After several years of development and field testing, we launched our "New Directions" curriculum, which emphasizes such direct care skills as relationship building, structuring the therapeutic environment and identifying and preventing crisis situations. In the event a client demonstrates a clear danger to self or others, we have also developed a Crisis Prevention and Intervention (CP/I) program which emphasizes the safe and humane application of a series of approved interventions. Each

Devereux Center not only provides comprehensive front-end training, but also schedules mandatory, periodic updates.

The staff at Devereux believe that treatment begins within the confines of a compassionate and caring treatment milieu. This protects the rights of the individual clients as well as those of their staff and treatment peer group. Accordingly, we do not view seclusion and restraint as "treatment" interventions per se, but rather, as emergent responses to dangerous situations. Our organization is very concerned about the inappropriate application of seclusion and restraint in any care setting and we have just completed the first year of work on an internal Task Force which was convened to study this critical area. The Task Force was commissioned in June, 1998, to evaluate Devereux's entire Crisis Prevention and Intervention (CP/I) curriculum against the backdrop of the current research literature and the contemporary community standards for the use of special treatment procedures with populations treated by Devereux programs.

We are now working to integrate these findings into each Center's day-to-day operations, as part of our Foundation-wide Quality Improvement program. Frankly, we believe the best way to decrease the utilization of these procedures is through both mandated staff development and training programs which emphasize positive management techniques and through the application of "Best Practices" which have been well-documented in research literature as producing positive client outcomes for given client populations. It is with these efforts in mind that I am writing to you today to comment on the above-referenced rule and its application to both hospital-based programs and the under-21 Medicaid population.

As part of our Task Force planning, we are seeking the services of an outside consultant to evaluate each part of the CP/I program and to assist us to implement modifications which have been identified as areas for improvement. In our ongoing efforts to have Quality Improvement data make an immediate, positive contribution to client care, special treatment procedure information is collected monthly at each Center and is aggregated and compared across the Foundation with other like client populations or "affinity" groups. Devereux has also established a "zero tolerance" expectation for client injury during the application of any physical treatment intervention, and our treatment professionals monitor each occurrence of seclusion or restraint at the program and Center levels. Internal "Quality Site Visits" conducted by senior clinicians and administrators provide concrete information regarding each Center's overall compliance with these expectations, as well as prompting specific consultation and design for corrective actions to bring each Center into full compliance. We believe these mechanisms are working well, provide "value-added" improvements to our clinical programs and facilitate the ongoing safety of both our clients and our staff.

However, there are some specific portions of the regulation that are new for our operation and which will create additional burdens or obstacles, which cannot be addressed easily by creating new policies and procedures or revising existing documents. If the stated intent of the new

regulations are to mirror Joint Commission on Accreditation of HealthCare Organizations (JCAHO) standards, there appears to be a significant departure in the stated "one-hour" rule. Further, the proposed stipulation permitting only physicians to make that assessment for the under-21 population is additionally problematic. In addition, I have significant concerns about the broadly based definitions proposed for the terms "seclusion" and "restraint."

Let me begin by sharing my perspective on those definitional issues. It appears the proposed definition of "seclusion" equates an intervention widely used by parents such as separating an angry child from his peer group until he has calmed down with a locked seclusion which might be utilized as an intervention in a behavioral health care setting. Many of the clients with whom we work require occasional redirection to take time away from a group activity if they have become upset. Should they remain upset after a few moments, a staff member might intervene with them, suggest ways to and direct them to remain apart from the group until they have achieved greater calm. Is this to be defined as a "seclusion" within the purview of the proposed regulation? I have additional concerns about defining "restraint" as including physical holding, mechanical restraints and medication used to achieve behavioral control. Each of these interventions may represent very different risks and create vastly different outcomes based upon the age and disability of that client. Should an intervention such as holding a small child carefully in a lap in order to demonstrate physical support for his efforts to achieve control require the same level of medical oversight as the use of mechanical restraints? We believe the client's treatment plan should include a listing of interventions which are individualized to achieve the desired therapeutic outcomes. Those interventions which are the most problem-prone should require the highest level of medical oversight with correlative levels of clinical documentation. We must use our medical staff in the areas of patient care which will most benefit from their unique training and expertise. Therefore, I urge you to reconsider the currently proposed definitions and adjust them to reflect the individualized treatment needs of the wide variety of client groups who receive treatment supports in other than hospital settings.

Secondly, I would like to comment on the "one-hour rule." Our interdisciplinary treatment model involves physicians in the development of the individualized plan of care as well as in the initiation and continuation of seclusion and restraint. Through care planning meetings, progressive responses to an individual client's anticipated escalations around key clinical issues are identified, strategized and implemented. Crises are addressed through approved Behavior Management Programs to which the physician and other team members provide input. Implementation of the approved plans are under the direction of credentialed and experienced treatment professionals, in consultation with the treating physician. This new standard not only dictates medical practice by requiring face-to-face assessments in all instances, but also does not consider the existing professional supports in the treatment setting. In fact, most situations can be addressed appropriately by telephonic consultation between the physician, the nurse and the other team members who have demonstrated competence to provide input to appropriately inform the physician. The physician must be able to make clinical judgments based upon his overall

assessment of the current circumstance, as compared to the his awareness of the overall presentation of the client. In addition, the standard does not take into account the feasibility of implementing this regulation in small and rural programs, where physician time is extremely difficult to engage, as well as extremely costly.

Extending this regulation to the under-21 Medicaid population would result in a "trickle-down" effect, severely limiting the access to care as many providers would be unable to secure required physician services on a 24-hour on-call basis. Indeed, this requirement would be difficult for most hospitals to meet, except for designated teaching hospitals, which have 24-hour availability of residents and interns. As such, this represents a substantial change in our current practice as well as a substantial increase in our operating costs. It is difficult to accept the summary of HCFA's impact analysis which reported that 80% of the hospitals would not be affected by this provision because of their JCAHO accreditation participation. I would like to suggest that HCFA conduct a thorough impact analysis of both hospitals and non-hospital environments which provide services to the under-21 Medicaid population. Should this regulation be implemented for the latter population, Devereux will have to analyze each program and each population we treat to ensure we can be fully compliant. I am certain this may result in a decision to discontinue treating some notch groups who desperately need treatment services.

My final major concern resides with the proposed regulation which would permit only licensed physicians to order and to continue seclusion and restraint. Our Foundation employs an interdisciplinary group of skilled professionals, each of whom must complete a rigorous credentialling process, to implement our clinical programs and to work with individual clients. As such, each treatment team member provides vital input to the treatment planning process and has significant awareness of the client's ever-changing condition. Particularly in our rural and non-hospital programs, these professionals work in consultation with the physician to deliver the care outlined in the treatment plan and to respond to crisis occurrences. They have daily contact with the client and can provide additional understanding regarding the least restrictive methods which may be utilized to provide a positive response to the emergent situation. In consultation with the nurse and with the physician as necessary, the "licensed independent practitioner" may then provide guidance regarding the therapeutic approach and the criteria for release of the patient from seclusion or restraint. This system works for our Foundation and allows us to provide appropriate care to clients in settings where on-site, 24-hour physician coverage is unfeasible. Because we anticipate the continuation of these operating policies, a related concern is the official HCFA definition of the "licensed independent practitioner." I would urge you to publish a formal definition of this staff category to avoid disclarity as we move forward.

In closing, please be assured that I am pleased to have been afforded the opportunity to comment on the proposed regulations. I appreciate your stated intent to allow flexibility and creativity for the effective implementation of the requirements without undue burden. I urge you to consider very carefully the "trickle-down" effects of both the "one-hour rule" and the "physician-only"

requirement for the initiation and continuation of seclusion and restraint, as I am quite concerned that both have dramatic access to care implications for some of our most severely impaired and needy clients.

Sincerely,

Ronald P. Burd
President & CEO

hb

STATEMENT OF THE FEDERATION OF FAMILIES FOR CHILDREN'S MENTAL HEALTH

The Federation is strongly opposed to the use of physical, chemical, or mechanical restraints and seclusion with any child but especially for children and youth who have mental, emotional or behavioral disorders or children and youth who have been exposed to violence. We view 1 restraint and seclusion as inhumane, cruel, and ineffective. These techniques, at best, may temporarily relieve stress for the adults in charge and always increase stress for the child or youth. There is no evidence that the use of restraints or seclusion has any therapeutic benefit whatsoever.

Restraint and seclusion are not appropriate forms of treatment. Children and youth who are "out of control" need services, supports, and highly specialized attention—not seclusion. When implementation of an IEP, service, or treatment plan fails to achieve the desired or appropriate behavior there must be a review and revision of the plan. Subjecting a child or youth to restraints and seclusion in such situations is equivalent to punishing the victim. No service or treatment plan should EVER include provisions for the routine use of seclusion or restraints. Seclusion or "time out" or any form of restraint are punishments that should be eliminated from the behavioral contracting and discipline protocols of schools, day and residential treatment centers, group homes, hospitals, and juvenile detention and correctional facilities.

Holding children should be a loving act not a violent one. Restraining children teaches them that it is acceptable to treat others with physical force when they do things you don't like. This is a very bad message. Children and youth, whose behavior is (or appears to be) very difficult for them and those who care for them to control need first and foremost a comprehensive assessment to learn what is causing this behavior and also to learn what function it is serving. A specific and individualized service plan consisting of effective therapeutic, medical, social, educational, and rehabilitative supports and services can then be drawn up by the family and youth along with their team of service providers and advisors. Such a plan must build on the child's and family's strengths and address the behavioral issues of greatest concern to them first. The over arching goal of any service plan should be to support the child and family so the child can live safely at home (or as close to home as possible), go to school and be successful in the general curriculum, and fully participate in the cultural, spiritual, and recreational life of the community.

Time out must be distinguished from seclusion. We would define time out as giving the child or youth the opportunity to temporarily and VOLUNTARILY remove her or himself from a situation to PREVENT further escalation of stress or anxiety. Time out must also be supervised and the child should be allowed to talk to a professional or supportive and rusted adult if she or he so wishes. Time one should end when the child feels ready to return to the group.

There may be rare instances where safety makes it necessary to use seclusion or restraints such as in a life threatening situation where there is absolutely no other way to safely protect a child whose behavior is violent or insure the safety of others

who are in danger from that behavior. In such cases only the responsible chief administrator or attending physician should authorize the procedure and:

- the child should NEVER be left alone—professional staff (not child care attendants or peers) trained in de-escalation and conflict resolution should be working with the child throughout the episode;
- seclusion should be ended or restrains be removed as soon as the behavior begins to subside AND an effective therapeutic intervention should be initiated within no more than 15 minutes of the onset of the incident;
- the child's parents or family should be notified as soon as the seclusion or restraint is initiated;
- the IEP, service, or treatment plan should be reviewed within 24 hours and revised if necessary.

There should be no instances of seclusion or restrain that last more than a few minutes (i.e. 15 minutes). If they do, the child should have ready (on demand) access to food, water, bathroom facilities, and be allowed to make a phone call to a predetermined, trusted, family member, professional, or support person. Any child who is secluded for more than 15 minutes should be provided with appropriate and safe learning materials and instruction.

All uses of restraints or seclusion should be immediately documented in the child's file and a copy of the report should be provided to the child's parent or guardian within 24 hours of the incident. The child's family should be allowed to insist that restraints and seclusion not be used for their child under any circumstances and this should not jeopardize the child's admission to or treatment at the facility.

Statement of the National Alliance for the Mentlly Ill

[SUBMITTED BY LAURIE FLYNN, EXECUTIVE DIRECTOR]

We commend Senator William Roth (R–DE) for his prompt action in convening a hearing of the Senate Finance Committee following the release of the General Accounting Office (GAO) report on October 1, 1999 on the improper use of restraints or seclusion in psychiatric facilities.

It has been one year since The Hartford Courant published its investigative series, inspired by reports from NAMI Connecticut families, which documented 142 deaths around the country from such abuse during a ten year period. The Harvard Center for Risk Analysis further indicated that between 50 and 150 such deaths occur every year.

NAMI also has compiled Cries of Anguish, a summary of additional reports of abuse received since the Courant investigation—cited in the GAO Report—which includes over 40 incidents from 20 states. During one five month period, five deaths were reported—four of them of youths under the age of 18. And those are only the ones we know about.

Legislation has been introduced in Congress. After today, two Senate hearings will have been held. The Department of Health & Human Services has published regulations for Medicare and Medicaid funded hospitals and is in the process of developing regulations for residential treatment centers. In spite of HHS's regulatory initiatives, there still are no consistent national regulations governing restraint and seclusion use in all facilities providing psychiatric treatment. The GAO has confirmed what many of us already knew over a year ago.

Not only is the current system broken—but indeed, there is no system. Most importantly, no comprehensive reporting system exists. It is both a national disgrace and a national crisis. Literally, people are dying. Others are being physically injured. Others are being psychologically scarred for life.

People will not be fully protected unless Congress passes a law to end the current system of horrors. Regulations are not enough, because too often, they are too easily changed. The issue today is not whether Congress should act, but when? How many more people must die before Congress acts? We hope this hearing will be used as a foundation for decisive action in the weeks ahead. NAMI calls on Congress to mandate the reporting of all deaths and serious injuries to state based legal entities which can investigate the circumstances of such incidents. Further, consumer and family facility monitoring groups should be put in place.

Prepared Statement of the National Association of Psychiatric Health Systems

SUBMITTED BY MARK COVALL, EXECUTIVE DIRECTOR]

When people come for treatment for psychiatric problems, they expect—and deserve—quality care. It's a given that people should expect to be treated with respect, dignity, and an understanding of their individual needs. That's the goal of the treatment providers that are part of our association: the National Association of Psychiatric Health Systems (NAPHS).

We are saddened—and determined to find a solution to system problems whenever something occurs that shakes the foundation of the trust and faith that people have in the treatment system.

Over the past year—and as this committee is hearing today—the inappropriate use of restraint and seclusion has surfaced as an area of concern. The issue has been brought to public consciousness through a number of channels—both professional and public.

We now need to address the inappropriate (and let me stress that word inappropriate) use of restraint and seclusion in a thoughtful way—and we are committed to doing that. But first, we need to be clear about what the issues are so that we can successfully encourage positive change and track how things are going.

What we shouldn't do—and can't afford to do—is to rush to judgment with "fixes" that generate more problems than they solve.

Let me be more specific about the issues as I see them.

THE ISSUES

First, we need to be clear about what restraint and seclusion are. The fear has been that these are barbaric tactics to coerce, constrain, or even punish people. That fear needs to be erased. We believe that restraint and seclusion are emergency interventions designed to protect patients in danger of harming themselves or others and to enable patients to continue treatment successfully, safely, and effectively. This is a fundamental principle in the Guiding Principles on Restraint and Seclusion for Behavioral Health Services that we developed with the American Hospital Association and widely distributed as part of our own efforts to encourage the field to ensure that their policies and practices are up to date and working well. Joint Commission policies—which govern hospitals and many other treatment settings—provide a similar definition. We totally agree that the use of these interventions should only be for safety—and only when other less restrictive methods are considered and are not feasible.

We need to be clear that advocates and providers share the same goal: reducing the need for and the use of restraint and seclusion. Through our policies and procedures (for example, as required by the Joint Commission), we all strive to use restraint and seclusion as infrequently as possible.

Yet we need to also be clear that there are times when restraint or seclusion may be the only way that we can ensure safety—of patients, families, and our own staffs. Restraint and seclusion, when used properly, can be life-saving and injury-sparing interventions. Picture a child about to gouge out an eye—to do irreparable harm to himself. Or picture yourself as a staff member trying to care for an adult high on PCP—hallucinating that you are the devil and threatening with superhuman strength to throw chairs or tables at you or other patients. Then you can understand why—in some circumstances—restraint or seclusion may be necessary to ensure safety. Treatment cannot proceed if the individual and the environment are not safe.

Mental illnesses are brain disorders, and as such, they do cause people to struggle with very tough challenges. Cognitive impairments can play out in behavior for example, paranoia that others are out to hurt you delusionsfear, anxiety, and severe panic attacks. These are all among the very real problems that can create a temporary state in which an individual may need an emergency intervention to help in regaining composure. While we would always want to try other methods of intervention first, there may be times when—for a variety of solid clinical reasons—these interventions may be the most appropriate ways to ensure safety in an acute moment in time so that treatment can resume as quickly as possible.

Anything that prevents clinicians from using medical judgment and from doing what they know is the right thing to do for any single patient—or that forces them to do the same thing for all patients, even when it's not necessary—is a tragic waste. Government should not be in the business of dictating medical practice. Your role as government leaders (through the work of HCFA, GAO, Congress, and Mrs. Gore) has helped to elevate the issues to the national agenda—and we applaud your

work. We are anxious to join with you in finding solutions. But we need to be sure that the solutions we propose—whatever they are—really do address specific problems and avoid unintended consequences (such as eliminating the use of restraint in treatment settings so that people with mental illnesses end up in jails instead).

HOW TO ENCOURAGE CHANGE THAT WILL MAKE A DIFFERENCE IN PEOPLE'S LIVES

As providers we strongly believe that standards relating to restraint and seclusion must build on what we know works. From our clinical experience, what truly changes practice are:

- strong organizational leadership
- a culture committed to reducing the use of restraint and seclusion
- trained and competent, well-qualified staff
- adequate staffing
- well-developed internal quality monitoring systems

We believe that resources committed to strong education and training of the staff who are on the front line, familiar with the patient, on hand when behavior is disintegrating, and able to learn and implement both de-escalation techniques and appropriate interventions (only when and if necessary) are really the best and most effective use of resources.

There is no empirical evidence to suggest that highly prescriptive requirements will have any effect—or even a good effect. There is no agreement in the field, for example, on the controversial provision in the hospital Conditions of Participation requiring a physician or licensed independent practitioner to do a face-to-face evaluation of every patient within an hour of the restraint or seclusion. Such a provision makes no sense for hospitals and—if imposed on other levels of care would have devastating, unintended consequences.

Care must be individualized, and no standard should usurp that principle.

NEW SYSTEMS RELATING TO RESTRAINT AND SECLUSION ARE NOW IN PLACE; WE NEED TO GIVE THEM TIME TO WORK

One very positive result of the national discussion that has emerged recently on the subject of restraint and seclusion has been the specific evolution of regulatory and accreditation solutions that we believe are having and will continue to have a positive effect.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which accredits hospitals and other treatment settings, has instituted a strong "sentinel event policy." JCAHO has established a system for accrediting organizations to report adverse incidents and their analyses of the events ("rootcause analyses") as a way of helping facilities to avoid future occurrences. This process is confidential, which encourages full reporting. Full reporting is the goal we believe is critical to improving care overall. In fact, we believe the JCAHO process could be improved if Congress would enact peer-review protections for root-cause analyses. Through the sentinel event reporting process now in place, JCAHO has already provided information to the field on problems—with warnings about what doesn't work. This system needs to be given a chance to work.

The JCAHO Task Force on Restraints is working on strengthening current standards on restraint and seclusion. JCAHO is in the process of soliciting comments from the field and will soon implement tougher standards based on a very thoughtful and rigorous discussion by all the constituencies affected by this issue—including consumers and providers.

This year, the Health Care Financing Administration (HCFA) also released new hospital Conditions of Participation and has indicated that they will issue regulations on non-hospital providers through the "under 21 benefit" for Medicaid. We fully support the overall thrust of the hospital Conditions of Participation on Patient Rights (with one major exception), and we believe that the regulatory process is the right way to deal with complex issues of oversight. We have all—consumers, providers, families—tried to suggest the best solutions within this process. We must be very thoughtful as we sort through the recommendations and move toward implementation.

Our single area of concern with the hospital Conditions of Participation is a provision that would require a physician or licensed independent practitioner to physically be on site within an hour of every restraint/seclusion intervention regardless of the medical necessity. We believe this is an example of a well-intentioned idea creating an overly prescriptive and unworkable response that destroys a system that is working well.

One of our primary objections to this so-called "one-hour provision" is that it was never included in the original proposed rule on the Conditions of Participation pub-

lished in December 1997. We are so concerned that such a fundamental change from current practice (and JCAHO standards) never went through the formal rulemaking process that NAPHS recently filed, together with the American Hospital Association, a lawsuit against HCFA. At the very least, time must be afforded to all parties concerned to provide thoughtful commentary and analysis on such a substantial and sudden change in standards.

State licensing bodies and other national accrediting agencies also play an important role in oversight of the use of restraint and seclusion, and we believe these are the organizations that have the expertise and the ability to do the job.

We believe that HCFA, JCAHO, other accrediting bodies, and state licensing agencies are the organizations that are—and should be—charged with oversight. They must be given the resources to do the job they are already empowered to do. What we don't need is duplicative and costly re-invention of these same agencies.

There are several legislative proposals pending before Congress concerning the use of restraint and seclusion. We do not believe, however, that legislation is the best way to address this issue and would only duplicate other efforts.

What we also don't need is to create barriers to using restraint or seclusion when it is necessary. We support the goal—of consumer and family advocates, professionals, and regulatory and accrediting bodies—to treat people in the least restrictive environment possible. But it is also important to recognize that as society implements this vision, the severity of problems being treated in lesser levels of care will be greater. Society's goal has been to avoid hospitalization if it is at all possible for a person to be managed in a lower level of care and to choose treatment over jail for individuals struggling with mental illnesses. If policies or leg;station inadvertently have the effect of preventing necessary and appropriate use of restraint or seclusion, children and adults will be sentenced to detention centers—rather than treatment. (In fact, an alarming number of people—particularly youngsters—with mental and addictive disorders are already in the juvenile justice system.) Exacerbating this problem is an unintended consequence that must be avoided. The experience of risk managers shows that the risk of not providing needed restraint or seclusion is higher than the risk of the use of these interventions. We should take no action that defeats the goal of treating people in the least restrictive environment possible for their specific needs.

FINDING BALANCE IN OVERSIGHT

What we do need is to develop standards that provide accountability without hindering patient safety or confidentiality.

We need to be able to dialogue with our colleagues (including consumers) about what works and what doesn't so that we can learn from and teach each other without fear of retribution or punishment or lawsuit.

We need to empower the multiple state agencies, national accrediting bodies, and regulatory agencies that already play a role in oversight to do their jobs. Creating duplicative, costly, and parallel systems does nothing to solve a problem. It only adds a bureaucratic burden that takes away resources from what should be our primary focus: patient care. This is even more true in an era of limited resources for behavioral health.

We need to design policy in a thoughtful way, not by responding emotionally to anecdotes about individual situations in which we have only part of the story. A case in point is a 60 Minutes piece aired earlier this year on the use of restraint and seclusion. While individual case examples can be enlightening overall, they don't get us to the real issues: how do we best regulate and oversee quality of care? What will really make a difference in people's lives—and what will simply be an administrative patch that makes us feel we're doing something—without measurable results . . . or worse, with unintended consequences?

We need to make certain that standards take into account the fact that different levels of care have different missions and resources. It is not appropriate—from either a clinical or financial perspective—to put the same standards and requirements on acute vs. non-acute care or to superimpose adult standards on children. Looking just at standards for use of restraint and seclusion with children and adolescents requires a thoughtful assessment of a variety of factors. For example, while generally descriptive of developmental stages, age distinctions alone would not be an appropriate way to set standards for young people. Developmental stages (rather than arbitrary age limits) are a more appropriate way to view the needs of children. For example, one 12-year-old may be dealing with issues related to childhood, while another 12-year-old may be 100 pounds heavier, sexually active, acting out violently, and generally dealing with issues that are related to adolescence. To arbitrarily say that certain interventions are not permitted solely because of age is to deny children

individualized treatment that takes into account their special needs and developmental stage. Regulations should not confuse brief physical interventions with restraint or seclusion. They are different—and are necessary. (We would describe these as "time outs" or "therapeutic holds" and believe that regulations must exclude these types of actions from any definition of restraint or seclusion. As any parent knows, there are times when children act out in ways that require immediate action. An adult may need to physically hold a youngster to prevent him or her from running into the street, or tell a child having a temper tantrum to sit quietly for a few minutes to gain composure. Treatment providers also need to be able to do a brief intervention to manage aggression (for example, to step in to break up a fight.) What is different about these actions is their brevity. Legislation and regulation need to recognize that "time outs" and "therapeutic holds" are very different.

We appreciate Senators Joseph Lieberman and Chris Dodd and other members of Congress for raising the issue of use of restraint and seclusion. We are committed to working with you and all others on this important issue.

About NAPHS

The National Association of Psychiatric Health Systems (NAPHS) represents behavioral healthcare systems that are committed to the delivery of responsive, accountable, and clinically effective treatment and prevention programs for children, adolescents, and adults with mental and substance use disorders. The organization was founded in 1933.

NAPHS members are behavioral healthcare provider organizations, including 400 specialty hospitals, general hospital psychiatric and addiction treatment units, residential treatment centers, partial hospital services, behavioral group practices, youth services organizations, and other providers of care. In 1999, the Association of Behavioral Group Practices (ABGP) merged with NAPHS, becoming a special-interest section within the association.

NAPAS National Association of Protection & Advocacy Systems

For Immediate Release

Contact: Paul Eagle
410-821-8220

NAPAS Says "Federal Restraint Legislation is Necessary to Bring Justice to Thousands of Our Most Vulnerable Citizens"

WASHINGTON, D.C. – (October 26, 1999) – The National Association of Protection and Advocacy Systems (NAPAS) commends the Senate Finance Committee for its hearings today on the misuse of seclusion and restraints in mental health facilities. Abusive restraint and seclusion practices result in more than 100 needless patient deaths each year and amounts to a national crisis in our system of care.

"We hope this hearing will help bring to light the wrongful deaths and injuries that have occurred with respect to our most vulnerable citizens. These incidents have occurred because there are no broadly applicable federal laws establishing national enforceable standards governing the use of seclusion and restraint and requiring that deaths and injuries be reported uniformly to investigative agencies," said Curt Decker, Executive Director of NAPAS.

"Fortunately there are bills pending in Congress, which could provide our advocacy agencies around the nation with an invaluable tool -- routine reporting of potential restraint-related deaths," said Decker They would also impose a set of minimum standards, which could save many lives."

"These bills are a call for justice for thousands of people with disabilities. I applaud these proposals – it's high time that we stopped this shameful abuse of restraint and seclusion, which has victimized our most vulnerable citizens," said Decker

An October 1999, U.S. General Accounting Office (GAO) report found that the lack of such a reporting requirement makes it impossible to determine the full extent of improper restraint and seclusion, and prevents independent agencies from investigating resulting deaths and injuries. Thus, the GAO recommends that federal regulators establish, in addition to broad protections against abusive restraint and seclusion practices, a requirement for reporting to the Protection and Advocacy (P&A) System all deaths and serious injuries which may be related to these practices -- so that P&As can conduct independent investigations.

The P&A System is a nationwide network of disability rights agencies with unique authority to investigate abuse and neglect of people with disabilities. The following are some facts about the P&A System:

-more-

900 Second Street, NE, Suite 211 Washington, DC 20002 (202) 408-9514
FAX: (202) 408-9520 TTY: (202) 408-9521
Website: http://www.protectionandadvocacy.com
E-Mail: napas@vipmail.earthlink.net

7010 Security Blvd.
Baltimore, MD 21244

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- P&As are mandated under various federal statutes to provide legal representation and advocacy services to all persons with disabilities. Indeed, P&As, collectively, are the largest provider of legally-based advocacy services to people with disabilities.

- A fundamental mandate of the P&A System is to investigate reports of abuse and neglect in facilities that serve persons with disabilities. P&As have authority to access the records of individuals in these facilities and to monitor facility conditions relating to health and safety. They may initiate an investigation if there is evidence presented to them of abuse and neglect, and are authorized to pursue all appropriate remedies to ensure that the human and civil rights of persons with disabilities are protected.

- In fiscal year 1998 alone, P&As responded to about 34,450 reports of abuse and neglect.

- P&As also devote considerable resources to ensuring that people with disabilities have full access to inclusive education programs, financial entitlements, health care, housing and employment opportunities.

- About 98 percent of P&A cases are resolved voluntarily, without resort to litigation.

- In fiscal year 1998, P&As assisted almost 70,000 individual clients nationwide, and provided some form of service to about 700,000 individuals with disabilities and their family members.

For more information about the P&A System, call 202-408-9514 or 202-408-9521 (TDD) or see our webpage at www.protectionandadvocacy.com.

# # #

Curt Decker is available for comment today

STATEMENT OF HON. PETE STARK

Mr. Chairman:

Thank you for holding this hearing today which will help educate Members and the public concerning the need for comprehensive restraint and seclusion standards and uniform reporting requirements.

As we will hear today, the misuse of restraints and seclusion is a very real problem. The series of Hartford Courant articles from October 1998 highlighted the misuse of restraint and seclusion in residential facilities over the course of the past ten years. The Courant reported that 142 cases of patient deaths over the past ten years were related to the use of restraint or seclusion.

The General Accounting Office's (GAO) September 1999 report on restraints and seclusion not only reaffirms the Courant's findings, but also finds that the number of deaths reported may be underestimated because reporting is so fragmentary. The GAO's survey of state Protection and Advocacy agencies identified 24 deaths during fiscal year 1998 related to restraint or seclusion. But the GAO concluded that it is impossible to determine all deaths in which restraint or seclusion was a factor because not all states require facilities to report restraint-related deaths and for those states which do require reporting, wide variation exists. The GAO also concluded that—based on the experience of several states—regulatory protections and reporting requirements can reduce the use of restraint and seclusion and improve safety for patients and staff.

Earlier this year, I joined Rep. DeGette to introduce legislation addressing the use of restraint and seclusion in Medicare and Medicaid institutional and residential facilities. Our legislation, the "Patient Freedom From Restraint Act of 1999" (H.R. 1313), would not prohibit the use of restraint or seclusion, but identifies the condi-

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tions when they may be used. The only time that such measures are warranted occur when the person's behavior creates an immediate threat to the health and safety of the patient and others. Our legislation would also require that treatment facilities document the use of restraint and seclusion in the patient's treatment or medical record. In addition to reporting the incident, the staff of the facility must document use in a treatment plan to reduce the future risk of episodes requiring restraint or seclusion.

Our bill would also require that residential facilities train their staff in the appropriate use of restraint techniques and its alternatives. We believe that this is an essential feature of the bill. Many of the deaths and severe injuries that patients experience result from misuse of standard restraint procedures. Finally, the legislation would require that cases of severe injury and death be reported to the state's Protection and Advocacy Board, and the Secretary of Health and Human Services. Documentation of these cases is an essential mechanism for protecting the rights and liberties of patients.

This past August, the Administration came forward with new conditions of participation for hospitals concerning the use of restraints. I commend the Administration for their important, major step forward to protect people in Medicare and Medicaid-funded hospitals. This is an important advance. Yet, as the GAO points out, we still have further to go because current federal regulations do not limit the use of restraint and seclusion in all settings such as residential treatment centers and group homes and there is no comprehensive reporting system to track injuries, deaths and use of restraint and seclusion.

The GAO report sheds light on the disturbing fact that the rights and safety of some of the most vulnerable of our society are still being needlessly placed at risk every day. At least one-third of reported deaths involve children—some as young as 12 years old. Federal rules must be strong enough to protect people of all ages regardless of the type of setting in which they are receiving care.

That is why, even with the new federal regulations, we still need to enact legislation. I can think of no better way to protect patients than to enact legislation which sets strict requirements for use of restraints and seclusion—including mandatory, comprehensive, uniform requirements for reporting deaths or serious injuries caused by restraints.

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